**CASE AUTH/1801/2/06**

# GENERAL PRACTITIONER v GLAXOSMITHKLINE

## Reference to a patient website

**A general practitioner complained about GlaxoSmithKline's involvement with the Ekbom Support Group (ESG), a support group for patients with restless leg syndrome (RLS). The complainant noted that GlaxoSmithKline had placed advertisements in the GP press drawing the reader's attention to RLS as a condition and advising that patients might like to know about the ESG website. The complainant understood that GlaxoSmithKline's product, ropinirole, would soon be licensed for the treatment of RLS.**

**The complainant noted that a newsletter on the ESG website referred to the use of ropinirole for RLS in Germany and the US and alleged that GlaxoSmithKline's advertisement might thus indirectly promote the product for use in a condition for which it had no UK licence. This seemed a cynical attempt, by a company with huge financial conflicts of interest, to exploit a patient support group.**

**The Panel noted that the advertisement in question was used from September 2004 until November 2005; it had only appeared in medical journals. GlaxoSmithKline had not informed patients or the public of the availability of the ESG website. In the UK ropinirole (GlaxoSmithKline's product Requip) was indicated for use in the treatment of Parkinson's disease.**

**The Panel noted that the ESG newsletter, October 2005, referred to ropinirole which was only licensed for RLS in Germany and the US. The newsletter predated the advertisement. The Panel noted that the ESG website included information about approaches for helping patients with RLS including medicines. There was no product licensed in the UK for RLS but it was anticipated that ropinirole would be so licensed by April 2006.**

**The Panel noted that it would have been a breach of the Code to include the information about the use of ropinirole in RLS in the advertisement as this would have constituted promotion of an unlicensed indication. On that basis, the Panel considered that referring health professionals to a website that included a newsletter giving information about an unlicensed indication in effect promoted that unlicensed indication. If that were not the case then companies would be able to refer to independent websites as a means of avoiding the restrictions in the Code. A breach of the Code was ruled which was appealed by GlaxoSmithKline.**

**The Panel considered that health professionals were encouraged to refer patients to the website. The Panel did not consider that this was unacceptable *per se*. The Panel did not consider that the material on the website was an advertisement for ropinirole *per se* and so no breach of the Code was ruled. The Panel noted, however, that the news section of the website referred to an article, published in December 2004, which reported that ropinirole was 'safe and effective for the treatment of RLS'. On that basis the Panel considered that GlaxoSmithKline was, in effect, directing patients to a site that contained misleading messages about the safety of ropinirole in an unlicensed indication which might indirectly encourage patients to ask their doctors to prescribe it. As above, if this were not the case then companies would be able to use independent websites as a means of avoiding the restrictions in the Code. A breach of the Code was ruled which was appealed by GlaxoSmithKline.**

**The Appeal Board noted that the advertisement which appeared in medical journals suggested that '… patients might appreciate being made aware of the Ekbom Support Group, which can be accessed via the internet at [website address given]'. GlaxoSmithKline was thus effectively directing both health professionals and members of the public to the website. Patient groups were not covered by the Code and thus material on their websites was a matter for the relevant patient group. Directing people to such sites, in pharmaceutical company advertising meant that the company became inextricably linked with the content of those sites whether or not they had had any input, control etc. If this were not the case then companies would be able to refer to independent websites as a means of avoiding the restrictions in the Code.**

**The Appeal Board noted from GlaxoSmithKline that when the advertisement was approved in August 2004, GlaxoSmithKline had checked the ESG website to ensure that directing health professionals to it did not lead to a breach of the Code. GlaxoSmithKline stated that it knew that the**

**newsletter on the website would be updated approximately every six months. The advertisement ran for 15 months – September 2004 until November 2005 – but GlaxoSmithKline did not recheck the website throughout that time. The Appeal Board considered that companies referring to patient group websites in their advertising needed to ensure that whenever they did so the website content was acceptable as far as the Code was concerned.**

**The Appeal Board noted that the ESG newsletter, October 2005, referred to ropinirole which was only licensed for RLS in Germany and the US. Although the product was not so licensed in the UK it was available, and licensed, for use in the treatment of Parkinson's Disease. GlaxoSmithKline's representatives confirmed that patients with RLS were often treated off-label.**

**The Appeal Board noted that it would have been a breach of the Code to include the information about the use of ropinirole in RLS in the advertisement at issue as this would have constituted promotion of an unlicensed indication. On that basis, the Appeal Board considered that referring health professionals to a website that included a newsletter giving information about an unlicensed indication in effect promoted that unlicensed indication. The Appeal Board thus upheld the Panel's ruling of a breach of the Code. Similarly, by encouraging health professionals to refer patients to the website the Appeal Board considered that GlaxoSmithKline was in effect directing members of the public to a site which contained statements which might encourage them to ask their doctors for ropinirole. The Panel's ruling of a breach of the Code was upheld.**

A general practitioner complained about the involvement of GlaxoSmithKline UK Limited with the Ekbom Support Group (ESG), a patient support group for patients with restless leg syndrome (RLS). The complainant noted that GlaxoSmithKline had placed advertisements (ref RLS/DPS/04/14400/1) in the GP press which drew attention to RLS, focussing in particular on the associated sleep disturbance. The advertisement stated there was currently no licensed treatment for RLS but that patients might like to know about the ESG; the website address for the group was given.

## COMPLAINT

The complainant was concerned about GlaxoSmithKline's involvement with the ESG. The Ekbom website, which GlaxoSmithKline had promoted in the GP press, offered advice on RLS. GlaxoSmithKline had a treatment, ropinirole, which was unlicensed for RLS in the UK but which the complainant understood might be licensed soon.

Ekbom was clearly a genuine patient group which was very well intentioned. A newsletter on its website, however, stated 'I know many members are now able to have ropinirole, but it is only licensed in Germany and the USA at present'. Ekbom also had a forum that members used.

The complainant was concerned about GlaxoSmithKline's involvement and that the advertisements in the GP press might indirectly be construed as promoting ropinirole for an unlicensed indication in the UK. This also seemed a cynical attempt to exploit a patient support group from a company which had huge financial conflicts of interest.

When writing to GlaxoSmithKline, the Authority asked it to respond in relation to Clauses 3.2, 20.1 and 20.2 of the Code.

## RESPONSE

GlaxoSmithKline submitted that the ESG was an entirely independent group which managed and produced its own website without any influence or input from GlaxoSmithKline apart from the RLS patient information leaflet which provided information on RLS but did not refer to any medicines; GlaxoSmithKline's involvement with the leaflet was clearly stated on the website copy and on the hard copy available from the ESG. The ESG collated information from various sources on a wide range of issues that affected sufferers of RLS and made it available via its website and other media to its members.

As the ESG was not a registered charity, no money had ever been given to it, its co-ordinator or other members by GlaxoSmithKline. Since 2004, GlaxoSmithKline had however provided:

- administrative support to transfer a handwritten database onto Microsoft Excel;
- installation of broadband internet connection;
- ESG headed stationery.

GlaxoSmithKline strongly refuted the allegation of a breach of Clause 3.2. The advertisement at issue was only published in professional journals between September 2004 and November 2005. The advertisement was strictly non-promotional and certified as such; it mentioned no product names and made no product related claims. The advertisement was intended to raise awareness among health professionals of RLS as a disease. A large (n=23,052) multinational investigation of primary care patients showed that 11.1% (n=2,564) had RLS and 3.4% (n=787) had significant disease (Hening *et al* 2004). 65% of RLS sufferers consulted for their illness but only 8-13% received a diagnosis of RLS. This clearly demonstrated that awareness of the condition was low and that it was in the interest of the public, as well as the whole healthcare sector, to raise awareness of the diagnosis of RLS. The advertisement informed health professionals that there was an alternative source of information available, ie the ESG. Written permission was provided by the founder and co-ordinator of the ESG to refer to the website.

This ESG was the only support group for patients with RLS in the UK and was a completely independent organisation. The website provided further information on diagnosis and a wide range of management options including non-pharmacological treatment. This website did not, in GlaxoSmithKline's view, promote any one treatment over another, and as mentioned above, the content did not receive any input from GlaxoSmithKline.

With reference to Clauses 20.1 and 20.2 the disease awareness advertisement was only ever placed in medical publications and therefore not aimed at patients. GlaxoSmithKline therefore refuted any allegations of a breach of either Clause 20.1 or 20.2.

Health professionals were informed about the ESG website so that they could find additional information, and if the need arose, patients could be directed to it, should the doctor concerned so choose. As detailed above GlaxoSmithKline considered that this was an important source of independent, balanced information.

Whilst there was information available on the website regarding the management of RLS, this covered a plethora of different remedies for RLS from lifestyle advice, herbal, dietary remedies and alternative medicine to a wide variety of prescription medicines. In addition, the advertisement clearly stated that there were currently no licensed treatments for RLS in the UK. This website provided balanced and accurate information to patients and its content was the responsibility of the ESG. The website received no input from GlaxoSmithKline (with the exception declared above) and did not preferentially favour one treatment over another.

In summary, GlaxoSmithKline denied any breach of the Code with regard to the relationship between it and the ESG and the use of non-promotional disease awareness advertisements. Ropinirole currently had a marketing authorization for use in RLS in the US, France, Switzerland and Australia.

Ropinirole, under the brand name Adartrel, received a positive recommendation from the European Medicines Agency (EMEA) Committee for Medicinal Products for Human Use (CHMP) in September 2005 under the mutual recognition procedure. The European Commission had now indicated its intention to ratify this positive decision by the end of March 2006 and it was anticipated that the Medicines and Healthcare products Regulatory Agency (MHRA) would grant a marketing authorization in the UK around the end of April 2006.

## PANEL RULING

The Panel noted that the advertisement in question was used from September 2004 until November 2005.

This case was considered under the requirements of the 2003 Code using the Constitution and Procedure in the 2006 Code of Practice booklet.

In the UK ropinirole (GlaxoSmithKline's product Requip) was indicated for use alone in the treatment of idiopathic Parkinson's disease. It could also be used with levodopa to control 'on off' fluctuations and permit a reduction in the total daily dose of levodopa.

The Panel noted that the advertisement only appeared in medical journals.

GlaxoSmithKline had not informed patients or the public of the availability of the ESG website. The advertisement to health professionals suggested that '… patients might appreciate being made aware of the Ekbom Support Group'.

The Panel noted that the ESG newsletter, October 2005, referred to GlaxoSmithKline's product, ropinirole, which was only licensed for RLS in Germany and the US. The newsletter predated the advertisement.

The Panel considered that companies referring to information on websites in their advertising needed to ensure that the website content was reasonable as far as the Code was concerned.

The ESG website included information about approaches for helping patients with RLS including medicines.

There was no product licensed in the UK for RLS but GlaxoSmithKline's product, Requip, was licensed elsewhere for RLS and it was anticipated that ropinirole would be so licensed in the UK by April 2006.

The Panel noted that it would have been a breach of the Code to include the information about the use of ropinirole in RLS in the advertisement to health professionals as this would have constituted promotion of an unlicensed indication. On that basis, the Panel considered that referring health professionals to a website that included a newsletter giving information about an unlicensed indication in effect promoted that unlicensed indication. If that were not the case then companies would be able to refer to independent websites as a means of avoiding the restrictions in the Code. Thus a breach of Clause 3.2 of the Code was ruled.

The Panel considered that health professionals were encouraged to refer patients to the website. The Panel did not consider that this was unacceptable *per se*. The Panel did not consider that the material on the website was an advertisement for ropinirole *per se* and so no breach of Clause 20.1 was ruled. The Panel noted, however, that the news section of the website referred to an article, published in December 2004, which reported that ropinirole was 'safe and effective for the treatment of RLS'. On that basis the Panel considered that GlaxoSmithKline was, in effect, directing patients to a site that contained misleading messages about the safety of ropinirole in an unlicensed indication which might indirectly encourage patients to ask their doctors to prescribe it. As in the matter considered above, if this were not the case then companies would be able to use independent websites as a means of avoiding the restrictions in the Code. A breach of Clause 20.2 was ruled.

## APPEAL BY GLAXOSMITHKLINE

GlaxoSmithKline appealed the Panel's rulings of breaches of Clauses 3.2 and 20.2 of the Code.

GlaxoSmithKline noted that this case concerned a disease awareness advertisement that it had run in the medical press to raise awareness among health professionals of RLS as a disease. The advertisement informed health professionals of the ESG as the only support group for patients with RLS in the UK, and referred to the ESG website.

GlaxoSmithKline noted that the complainant was concerned about the company's involvement with the

ESG and that advertisements in the medical press 'might be indirectly construed' as promoting ropinirole in an unlicensed indication. GlaxoSmithKline submitted that the complainant had not accused it of promoting ropinirole in an unlicensed indication *per se*, and this certainly was not its intention. The advertisement was non-promotional and did not refer to any pharmaceutical products as treatments for RLS and contained no product-related claims. The advertisement clearly stated that there were no licensed treatments for RLS in the UK.

GlaxoSmithKline strongly refuted the complainant's allegation that it 'seemed a cynical attempt to exploit a patient support group'. As previously stated, the ESG was an entirely independent organisation to which GlaxoSmithKline had provided only very limited support and never made any monetary payment. GlaxoSmithKline had never had any input to or influence over the content of the ESG website (except for the patient information leaflet as previously stated and explicitly declared). The ESG October 2005 newsletter to which the Panel referred was entirely the independent work of the ESG co-ordinator. It was added to the website in October 2005 and was therefore not present at the time the advertisement was certified (August 2004) and for the great majority of the period during which it ran (September 2004 to November 2005). Thus, there was only an overlap of one month whilst the advertisement was still running and the newsletter was present on the ESG website. As previously described, the fact that this appeared on the ESG website in October 2005 was unknown to GlaxoSmithKline and outside of its control. The reference to the ESG website was provided in good faith with the knowledge of the ESG and in the expectation that it would be a useful source of information for health professionals and any patients so referred.

In addition, GlaxoSmithKline submitted that whilst the October 2005 newsletter referred to ropinirole as a treatment for RLS, it was quite clear in stating that ropinirole was not yet licensed in the UK and did not in any way suggest that any one treatment was better or more effective than others ('There are now several drugs that are used for RLS but, as yet, none are licensed for it here …. Some are in more use than others but it does not mean they are any better or more effective …. I know many members are now able to have ropinirole, but it is only licensed in Germany and the USA at present'). Elsewhere the ESG website (sections on 'Remedies') covered information on a plethora of different remedies for RLS from lifestyle advice, herbal and dietary remedies, and alternative medicines to a wide variety of prescription medicines. Thus, the website was well balanced and did not promote or preferentially favour any one treatment for RLS over another.

GlaxoSmithKline submitted that in view of all these facts, this was clearly not an attempt to promote ropinirole in an unlicensed indication, either directly or indirectly. However, the ruling implied that GlaxoSmithKline had deliberately subverted the system to direct health professionals to the website to receive this information. GlaxoSmithKline accepted that had it directed health professionals to a website containing information on ropinirole in RLS, it would have been in breach of the Code, it had not done this and it was not its intent.

GlaxoSmithKline noted that its advertisement had been ruled in breach, not for its content but only for its reference to the ESG website. However, this was made in good faith in the interests of education and information provision. The changes to the website were totally outside GlaxoSmithKline's control and were made at the very end of the advertisement period without any knowledge of, or notification to, it. Indeed, if GlaxoSmithKline was inputting to the ESG it could have ensured that there was no mention of ropinirole on the website which it was unable to do. The ESG was not an agent of GlaxoSmithKline's, and therefore not bound by the Code. GlaxoSmithKline considered that it was unreasonable as part of disease awareness activities to be aware of changes made to such independent sites when its intent from the outset was clearly educational, and circumstances outside its control made information available on the ESG website. Moreover, in its ruling, the Panel had declared that the information on the ESG website was not an advertisement *per se*. Despite this, it had ruled a breach of the Code for promotion outside of the terms of a licence. This showed an inconsistency in the interpretation of the impact of the information on the ESG website and the ruling of a breach of Clause 3.2.

Thus, GlaxoSmithKline submitted that the Panel's ruling was overly strict when it was clear that it was not the intention of the disease awareness advertisement to direct health professionals or patients to ropinirole information in an unlicensed indication. GlaxoSmithKline therefore appealed the Panel's ruling of a breach of Clause 3.2 of the Code.

GlaxoSmithKline reiterated that the disease awareness advertisement was only ever placed in medical publications and therefore not aimed at patients. Health professionals were told about the ESG website, so that they could find additional information, and if they so chose, direct patients to it. As detailed above, this was an important source of independent, balanced and accurate information on RLS, including a range of different treatment options.

GlaxoSmithKline noted that the 'News' section had referred to Walters *et al* (2004); a large, multinational, double-blind, placebo-controlled study, which reported that ropinirole was 'safe and effective for the treatment of RLS'. This statement summarised the findings of this pivotal trial which showed that ropinirole significantly improved RLS symptoms, sleep, quality of life and was well tolerated.

GlaxoSmithKline repeated that the website content was the responsibility of the ESG (with the exception declared above), and it had no input, influence or knowledge of the placement of the reference to Walters *et al*. The paragraph was added on the 30 October 2005 which post-dated the great majority of the period during which the advertisement ran. In addition, the paragraph explicitly stated 'This information is intended for primary care physicians, neurologists, sleep disorder specialists, and other

specialists who care for patients with RLS', and therefore it was clearly not aimed at patients.

For these reasons, GlaxoSmithKline strongly refuted the allegation that it was, in effect, directing patients to a website that contained misleading messages about the safety of ropinirole in an unlicensed indication which might indirectly encourage patients to ask their doctors to prescribe it. The advertisement was never directed at patients but merely advised health professionals of the only support group (the ESG) for RLS patients in the UK. Overall, GlaxoSmithKline submitted that the content of the ESG's website was fair, balanced and broad and did not preferentially favour one treatment over another; and hence, did not encourage patients to ask for a specific medicine. GlaxoSmithKline therefore also appealed the Panel's ruling of a breach of Clause 20.2 of the Code.

## COMMENTS FROM THE COMPLAINANT

The complainant considered that the motivation of GlaxoSmithKline with this patient group could be in little doubt. The promotion of RLS went hand in hand with the promotion of ropinirole. This was standard marketing/sales activity seeking to generate new markets and was known as 'disease mongering'. Whether this activity was legitimate remained an ongoing debate.

The complainant accepted that although GlaxoSmithKline made no direct financial support to ESG, as a small patient group the provision of a broadband link, administrative support and stationery represented a large contribution overall. Furthermore, the publicity and profile afforded by GlaxoSmithKline's advertisements represented many thousands of pounds and was clearly beyond the reach any small interest group. This did not fit with GlaxoSmithKline's submission of 'very limited support'.

The complainant alleged that GlaxoSmithKline had used ESG to promote RLS and indirectly ropinirole (unlicensed at the time). The website referred to ropinirole and the complainant alleged that the discussion forums (which were not reviewed) were to refer to ropinirole as the quote from the newsletter highlighted 'I know many members are now able to have ropinirole'. GlaxoSmithKline had a responsibility not to promote ropinirole off-licence irrespective of the independence of ESG, even if the company alleged that it acted 'in good faith'. This argument could and would be used by other companies to defend similar activity in the future.

The complainant submitted that acceptance of the appeal would set a precedent that other companies could exploit using third party websites and the internet to side step regulations on the promotion of medicines. To restore public trust the Code must be vigorously enforced or the perception of Astro-Turfing would continue in regard to involvement with patient groups.

## APPEAL BOARD RULING

The Appeal Board noted that the advertisement which appeared in medical journals suggested that '… patients might appreciate being made aware of the Ekbom Support Group, which can be accessed via the internet at [website address given]'. GlaxoSmithKline was thus effectively directing both health professionals and members of the public to the website. Patient groups were not covered by the Code and thus material on their websites was a matter for the relevant patient group. Directing people to such sites, in pharmaceutical company advertising meant that the company became inextricably linked with the content of those sites whether or not they had had any input, control etc. If this were not the case then companies would be able to refer to independent websites as a means of avoiding the restrictions in the Code.

The Appeal Board noted from GlaxoSmithKline that when the advertisement was approved in August 2004, GlaxoSmithKline had checked the ESG website to ensure that directing health professionals to it did not lead to a breach of the Code. GlaxoSmithKline stated that it knew that the newsletter on the website would be updated approximately every six months. The advertisement ran for 15 months – September 2004 until November 2005 – but GlaxoSmithKline did not recheck the website throughout that time. The Appeal Board considered that companies referring to patient group websites in their advertising needed to ensure that whenever they did so the website content was acceptable as far as the Code was concerned.

The Appeal Board noted that the ESG newsletter, October 2005, referred to GlaxoSmithKline's product, ropinirole, which was only licensed for RLS in Germany and the US. Although the product was not so licensed in the UK it was available, and licensed, for use in the treatment of Parkinson's Disease. GlaxoSmithKline's representatives confirmed that patients with RLS were often treated off-label.

The Appeal Board noted that it would have been a breach of the Code to include the information about the use of ropinirole in RLS in the advertisement at issue as this would have constituted promotion of an unlicensed indication. On that basis, the Appeal Board considered that referring health professionals to a website that included a newsletter giving information about an unlicensed indication in effect promoted that unlicensed indication. The Appeal Board thus upheld the Panel's ruling of a breach of Clause 3.2. The appeal on this point was unsuccessful.

The Appeal Board considered that the Panel's ruling of no breach of Clause 20.1, ie that the ESG website did not constitute an advertisement for a prescription only medicine to the public, was not inconsistent with the ruling that the advertisement promoted an unlicensed indication to health professionals.

The Appeal Board considered that health professionals were encouraged to refer patients to the website. The news section of the website referred to an article, published in December 2004, which reported that ropinirole was 'safe and effective for the treatment of RLS'. On that basis the Appeal Board considered that GlaxoSmithKline was, in effect, directing members of the public to a site that contained misleading messages about the safety of ropinirole in an unlicensed indication which might indirectly encourage them to ask their doctors to

prescribe it. The Appeal Board thus upheld the Panel's ruling of a breach of Clause 20.2. The appeal on this point was unsuccessful.

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| **Complaint received** | **20 February 2006** |
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