PRIMARY CARE TRUST PHARMACIST v GLAXOSMITHKLINE

Patient poster on restless legs syndrome

A pharmacist at a primary care trust complained about a poster issued by GlaxoSmithKline, which asked 'Do you suffer from Restless Legs Syndrome [RLS]?' and went on to ask four other questions eg 'Do you have an urge to move your legs?' and 'Is it worse in the evenings or at night?'. Readers were told that if they answered yes to all of the questions then they might have RLS. They were advised to ask their doctor for advice. The GlaxoSmithKline logo appeared in the bottom right-hand corner.

The poster, issued to GP practices, was aimed at the general public and the complainant considered that raising the profile of RLS in this way was wholly inappropriate and misleading in its implication that it could be resolved. The complainant also alleged that the poster was misleading in that it would encourage patients who might, or who might not, be suffering from RLS to seek treatment for it from their GP. It would be more appropriate to encourage patients with the symptoms listed to seek advice rather than implying a diagnosis before they had even seen their GP.

The complainant stated that pharmacological intervention would only be required in an estimated 20-25% of patients with symptoms of RLS. In the majority of cases, non-pharmacological treatments were effective, but required a degree of commitment from patients. Patients were far more likely to request pharmacological treatment. The only licensed treatment for this condition was Adartrel, recently launched by GlaxoSmithKline.

The Panel noted that the poster encouraged readers to ask their doctor for advice as opposed to treatment. GlaxoSmithKline had sponsored the poster and also marketed Adartrel, a prescription only medicine for the symptomatic treatment of moderate to severe idiopathic RLS. Adartrel was not the only medicine so licensed. The Panel considered that although the poster raised awareness about RLS, and thus might facilitate the market development of Adartrel, it did not promote the product to the general public. No breach of the Code was ruled.

The Panel accepted that the poster might encourage patients to ask their doctors for advice about RLS but it did not encourage them to ask for a specific prescription only medicine. The Panel ruled no breach of the Code.

A pharmacist at a primary care trust complained about a poster (ref RLS/PSR/06/25194/1), issued by GlaxoSmithKline UK Ltd. The poster asked the reader 'Do you suffer from Restless Legs Syndrome [RLS]?' and went on to ask four other questions eg 'Do you have an urge to move your legs?' and 'Is it worse in the evenings or at night?'. Readers were told that if they answered yes to all of the questions then they may have RLS. They were advised to ask their doctor for advice. The GlaxoSmithKline logo appeared in the bottom right-hand corner. The poster had been distributed to 14,000 practice managers and 4,500 secondary care physicians.

COMPLAINT

The complainant noted that the poster, issued to GP practices for display, was aimed at the general public. Whilst increasing public awareness of diseases and other medical conditions was commendable when conducted appropriately, the complainant considered that raising the profile of RLS in this way was wholly inappropriate and misleading in its implications that there was a way in which it could be resolved.

It was also misleading in that the poster would encourage such patients who might – or more importantly who might not – be suffering from RLS to seek treatment for it from their GP. It would be far more appropriate to encourage patients with the symptoms listed to seek advice on what might be causing them (eg pregnancy, iron deficiency, renal failure, diabetes and some medicines) rather than implying a diagnosis before the patient had even seen their GP.

This approach was of particular concern given the present therapies available for RLS, particularly when pharmacological intervention would only be required in an estimated 20-25% of patients with symptoms of RLS. In the majority of cases non-pharmacological treatments were effective but required a degree of commitment from patients coupled with lifestyle changes. Patients were far more likely to request pharmacological treatment, which in this case would put the GP in a very difficult position – to either prescribe an unlicensed product such as the majority of dopamine receptor agonists, an opioid or an anticonvulsant or to prescribe a licensed product. Presently the only licensed treatment for this condition was Adartrel, a prescription only medicine recently launched by GlaxoSmithKline. The complainant also considered this was particularly an issue given the black triangle status of the product. The legal classification of the product suggested that the poster might therefore be in breach of the Medicines and Healthcare products Regulatory Agency (MHRA Blue Guide, Section 5.2 (Medicines suitable for advertising to the public).

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

RESPONSE

GlaxoSmithKline disagreed with the complainant's position that the way in which it had tried to raise the profile of RLS was 'wholly inappropriate and misleading in its implications that there was a way in which it could be resolved'.

GlaxoSmithKline firmly considered that the poster provided no information which either directly or

indirectly advertised a prescription only medicine to the general public, and therefore strongly denied a breach of Clause 20.1.

GlaxoSmithKline considered that the poster was entirely appropriate in both its format and content and noted that:

- The poster provided information only to raise patients' awareness that this set of symptoms might indicate RLS, a recognised condition, and that they should consult their GP for further advice. GlaxoSmithKline agreed with the complainant that the GP would be expected to investigate for underlying causes, confirm or refute the diagnosis, and advise on either non-pharmacological treatment or pharmacological treatment as dictated by the patient's clinical status.
- The poster provided no information on, or implied as to which way the condition should be managed. In particular, the poster did not refer to any management interventions.
- There was no branding on the poster that coincided with that of any of GlaxoSmithKline's products.

GlaxoSmithKline also strongly denied a breach of Clause 20.2. The poster did not , either directly or indirectly, refer to any product nor any inference as to the need for treatment, be that non-pharmacological or pharmacological. Thus, GlaxoSmithKline firmly believed that the poster did not prompt patients to ask their doctor for a specific medicine, let alone one marketed by GlaxoSmithKline.

GlaxoSmithKline also noted that Adartrel was not the only licensed treatment for RLS. Pramipexole (marketed by Boehringer Ingelheim as Mirapexin), was granted a marketing authorization for the treatment of moderate to severe RLS on 5 April 2006, over one month before Adartrel received its licence for the same use.

In summary, the poster was developed with the sole objective of raising patients' awareness of a condition which was under-recognised and under-diagnosed. This under-recognition caused distress to patients and repeated consultations.

The poster provided no information on the way in which the condition should be managed, and in particular, did not either directly or indirectly refer to any specific product(s) or management pathways. These were matters between the physician and the patient based on the status of the individual. The poster merely stated that if patients answered 'yes' to the four mentioned questions (based on criteria developed by the International Restless Legs Syndrome Study Group) then they might have RLS and that the doctor should be asked for advice.

GlaxoSmithKline strongly refuted any breach of the Code and believed this poster to be within both the letter and spirit of the Code.

GlaxoSmithKline did not consider the complainant's point about the MHRA Blue Guide was relevant. The poster mentioned no products, but solely raised awareness about a disease area where there was more than one licensed therapy, as well as many established non-pharmacological management interventions, GlaxoSmithKline took the safety of all of its medicines extremely seriously, be they marked with a black triangle or not.

PANEL RULING

The Panel noted that the poster posed a number of questions related to RLS and encouraged those readers who had answered 'yes' to them to go and ask their doctor for advice. There was no direct or implied reference to medicines in the poster. In that regard the Panel noted that readers were encouraged to ask their doctor for advice as opposed to treatment. The Panel noted that Clause 20.1 of the Code stated that prescription only medicines (POMs) must not be advertised to the general public. GlaxoSmithKline had sponsored the poster in question and also marketed Adartrel, a POM for the symptomatic treatment of moderate to severe idiopathic RLS. Adartrel was not the only medicine so licensed. The Panel considered that although the poster raised awareness about RLS, and thus might facilitate the market development of Adartrel, it did not promote the product to the general public. No breach of Clause 20.1 was ruled.

The Panel noted the requirements of Clause 20.2 of the Code that information about prescription only medicines which was made available to the general public must be factual and presented in a balanced way. It must not raise unfounded hopes of successful treatment or be misleading with respect to the safety of the product. Statements must not be made for the purpose of encouraging members of the public to ask their doctors to prescribe a specific prescription only medicine. The Panel accepted that the poster might encourage patients to ask their doctors for advice about RLS but it did not encourage them to ask their doctor to prescribe a specific prescription only medicine. The Panel ruled no breach of Clause 20.2 of the Code.

Complaint received **30 May 2006**

Case completed **5 July 2006**