CONSULTANTS IN CHILD AND ADOLESCENT PSYCHIATRY v LILLY

Strattera Support Service

Two consultants in child and adolescent psychiatry complained jointly about a Strattera (atomoxetine) Support Service offered by Lilly and drew attention to a letter from the company which asked them to recruit their patients to the service.

The complainants alleged that the service involved pharmaceutical company employees having direct contact with patients to support carers of patients taking Strattera in the early phases; this was totally inappropriate. Such support should be provided by their clinicians and the complainants provided that support. The complainants were concerned that if pharmaceutical company employees had direct contact with the patients they would give them inappropriate and biased advice about the company's product.

The detailed response from Lilly is given below.

The Panel noted that it was not necessarily a breach of the Code for a pharmaceutical company to have direct contact with patients taking its medicines. Pharmaceutical companies had to ensure that prescription only medicines were not advertised to the public. Information about prescription only medicines made available to the public had to 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.

The Panel noted that the letter at issue introduced the Strattera Support Service as an initiative for supporting carers of children and adolescents prescribed Strattera for attention deficit hyperactivity disorder (ADHD) during the first 12 weeks of treatment. It was stated that the service was a Lilly initiative delivered in conjunction with a named service provider. The Panel queried whether the recipients would know who or what the service provider was. A patient/carer information sheet accompanying the letter referred to the delivery of the service by independent nurses and stated that the service was not intended to replace their doctor's advice or the package leaflet provided with the medicine. Neither the letter nor the accompanying patient/carer information sheet, however, made it abundantly clear that neither Lilly nor its representatives would have any direct patient contact. The letter stated that the service would offer telephone support for carers and patients, with a mutually agreed frequency. Neither the letter nor the patient/carer information sheet mentioned the follow-up calls at 6, 9 and 12 months referred to in Lilly's response. Lilly had submitted that the frequency of proactive and reactive contact was based on carer/patient needs, the requirements for which were discussed at first contact between the nurse and carer.

There were two referral routes. The first was initiated by clinicians who, having been introduced to the service by representatives and expressed an interest in it were followed-up by a manager or nurse employed by the service provider. The clinician would complete a service authorization document and thereafter refer patients who had been prescribed Strattera to the service. The patient/carer would then have to complete a consent form before they could be enrolled. The alternative route was patient initiated via pharmacies whereby a retail pharmacist could give the patient/carer a letter which explained how the service worked and provided a contact number. As above the clinician would still have to have signed the service authorization document and agreed to the patient being enrolled into the service before it could be delivered.

The information sheet provided to patients/carers described the service and made it clear that it worked alongside and did not replace doctor's advice and was provided by independent nurses. There was a clear declaration of sponsorship by Lilly.

The Panel noted that the service was designed to support patients and their carers. As a result of this service no gift, benefit in kind or pecuniary advantage was offered or given to members of the health professions as an inducement to prescribe, supply, administer, recommend, buy or sell any medicine. No breach of the Code was ruled.

The Panel noted that contrary to the complainants' allegation, Lilly employees had no direct contact with patients. All patient/carer contact was with a nurse employed by the service provider. Any data collected was aggregated and anonymised before being seen by Lilly. The Panel did not consider that the service and letter provided to patients was inappropriate or otherwise biased as alleged. The patient/carer was only told about the service once the prescribing decision was made and thus the provision of the service did not encourage them to seek a prescription for Strattera. No breach of the Code ruled.

During its consideration of this case the Panel observed that health professionals were sometimes concerned that pharmaceutical company

employees might have direct contact with patients via various service offerings. The Panel considered that, in introducing and describing their service offerings to health professionals, it would be helpful if companies made the position with regard to patient contact abundantly clear at the outset. Whilst companies were familiar with names of third party service providers, health professionals might not be.

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COMPLAINT

The complainants referred to a letter from Lilly which asked them to recruit their patients to the Straterra Support Service. The complainants alleged that the service involved pharmaceutical company employees having direct contact with patients to support carers of patients taking Strattera in the early phases.

The complainants considered that it was inappropriate for pharmaceutical company employees to have direct contact with patients. Such support when people took medicines should be provided by their clinicians and the complainants provided that support. The complainants were concerned that if pharmaceutical company employees had direct contact with the patients they would give them inappropriate and biased advice about the company's product.

When writing to Lilly the Authority asked it to respond in relation to Clauses 2, 9.1, 18.1 and 22.2 of the Code.

RESPONSE

Lilly considered that there had been a complete misunderstanding of how the Strattera Support Service operated.

The Strattera Support Service was a non-promotional programme provided by a service provider on behalf of Lilly. It was designed to provide telephone support to carers of children and adolescents with attention deficit hyperactivity disorder (ADHD) after the prescriber had decided to start the patient on Strattera. The service covered the first twelve weeks of therapy, with follow-up calls made at 6, 9 and 12 months. The frequency of proactive and reactive contact was based on carer/patient needs and requirements which were discussed at the first contact. The Strattera Support Service nurse was available during normal office hours.

Lilly submitted that from its national roll out in May 2008, the Strattera Support Service had been introduced to clinicians by its representatives. The representatives only gave a brief description of the service (in accordance with Clause 18), and if the clinician was interested in the service, all subsequent follow-up was carried out by the Strattera Support Service manager or one of the Strattera Support Service nurses, working for a service provider on behalf of Lilly. If the clinician wanted their patients to access the service they had to complete the Service Authorisation document and return it to the service provider. When this was completed the clinician could refer patients to the service.

When a clinician referred a patient into the service, a consent form had to be completed by the carer/patient before the Strattera Support Service nurse could enrol that carer into the service.

Therefore, a patient/carer could not be enrolled into the Strattera Support Service without the explicit consent of their clinician and the carer/patient, in each case after the patient had been prescribed Strattera.

As of 1 June 2009 patients could also be referred to the Strattera Support Service via a number of UK retail pharmacies which ran software linked to a database. When a pharmacist in such a pharmacy dispensed Strattera, additional information about the Strattera Support Service appeared on the screen, including a letter that could be printed off and given to the patient/carer. The letter explained how the Strattera Support Service worked and included the telephone number of a secure voicemail at the service provider. If a patient/carer telephoned this number to be enrolled in the service, the Strattera Support nurse would check if that patient's clinician had already signed up to the service. If they had, the nurse would obtain patient/carer consent. If the clinician had not previously signed up, the nurse would require the clinician to complete the Service Authorisation document as above. Once again, as above, the clinician had to sign the patient up to the programme before it could be initiated.

Lilly submitted that the letter at issue was sent to consultant and associate specialists in paediatrics and child and adolescent psychiatry as well as nurses with an interest in ADHD and consultants in learning difficulties. Lilly ensured that its mailing list did not contain the details of those who did not wish to receive promotional mailings from pharmaceutical companies.

Lilly submitted that the manager and the nurses recruited to work on this programme were all registered with the Nursing and Midwifery Council and as such were bound to its code of conduct. The manager and the nurses were all on the mental health part of the register and had experience of working in this area both in the NHS as well as with the service provider.

During the initial telephone call to the carer/patient, the Strattera Support Service nurses assessed the level of support that would be required. The nurse would telephone the carer/patient at mutually agreed intervals and the carer/patient could

telephone the nurse during office hours. The nurse's role was to provide support through the initial side effects that might occur on Strattera treatment. Any adverse reactions were reported to Lilly according to its standard operating procedures. Any data collected by the nurses was transmitted live to a secure server owned by the service provider and kept confidential.

The representative's role was limited to setting up initial appointments for the Strattera Support Service nurses – subsequent follow-up was carried out by the nurses themselves. Any data collected were aggregated and anonymised before being seen by Lilly. None of the service provider's payment for providing the service was contingent upon the generation of Strattera prescriptions.

Lilly submitted that the Strattera Support Service conformed to all aspects of the Code.
The service presented information to patients or carers in a factual and balanced way. Patients would only be enrolled after a decision had been made to prescribe Strattera and thus there could be no suggestion that members of the public were being encouraged to use or ask for Strattera. The Patient Consent Form was included to demonstrate that the programme was described in a factual and balanced way.

With regard to Clause 18.1, Lilly submitted that health professionals were not given any inducements to prescribe Strattera or sign patients up to the service. High standards had been maintained throughout with the service being conducted by professionally qualified nurses who had experience in mental health. The service provider maintained good standards, and all data that Lilly received had been anonymised. The company denied a breach of Clause 9.1. Lilly further submitted that as the Strattera Support Service met all the conditions of the Code no breach of Clause 2 had taken place.

In summary Lilly submitted that this case had arisen because the complainants did not understand how the Strattera Support Service was run: the service benefited patients and was run appropriately by a third party on behalf of Lilly, fully within the Code.

PANEL RULING

The Panel noted that it was not necessarily a breach of the Code for a pharmaceutical company to have direct contact with patients taking its medicines. Pharmaceutical companies had to ensure that prescription only medicines were not advertised to the public. Information about prescription only medicines made available to the public had to 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 (Clauses 22.1 and 22.2).

The Panel noted that the letter at issue introduced the Strattera Support Service as an initiative for supporting carers of children and adolescents prescribed Strattera for ADHD during the first 12 weeks of treatment. It was stated that the service was a Lilly initiative delivered in conjunction with a named service provider. The Panel queried whether the recipients would know who or what the named service provider was. A patient/carer information sheet accompanying the letter referred to the delivery of the service by independent nurses and stated that the service was not intended to replace their doctor's advice or the package leaflet provided with the medicine. Neither the letter nor the accompanying patient/carer information sheet, however, made it abundantly clear that neither Lilly nor its representatives would have any direct patient contact. The letter stated that the service would offer telephone support for carers and patients, with a mutually agreed frequency. Neither the letter nor the patient/carer information sheet mentioned the follow-up calls at 6, 9 and 12 months referred to in Lilly's response. Lilly had submitted that the frequency of proactive and reactive contact was based on carer/patient needs, the requirements for which were discussed at first contact between the nurse and carer.

There were two referral routes into the service. The first was initiated by clinicians who, having been introduced to the service by representatives and expressed an interest in it were followed- up by a manager or nurse employed by the service provider. The clinician would complete a Service Authorization document and thereafter refer patients who had been prescribed Strattera to the service. The patient/carer would then have to complete a consent form before they could be enrolled. The alternative route was patient initiated via pharmacies whereby a retail pharmacist could give the patient/carer a letter which explained how the service worked and provided a contact number to enrol on the service. As above the clinician would still have to have signed the Service Authorization document and agreed to the patient being enrolled into the service before the service could be delivered.

The information sheet provided to patients/carers described the service and made it clear that it worked alongside and did not replace doctor's advice and was provided by independent nurses. There was a clear declaration of sponsorship by Lilly.

The Panel noted that the service was designed to support patients and their carers. As a result of this service no gift, benefit in kind or pecuniary advantage was offered or given to members of the health professions as an inducement to prescribe, supply, administer, recommend, buy or sell any medicine. No breach of Clause 18.1 was ruled.

The Panel noted that contrary to the complainants' allegation, Lilly employees had no direct contact with patients. All patient/carer contact was with a nurse employed by the service provider. Any data collected was aggregated and anonymised before

being seen by Lilly. The Panel did not consider that the service and letter provided to patients was inappropriate or otherwise biased as alleged. The patient/carer was only told about the service once the prescribing decision was made and thus the provision of the service did not encourage them to seek a prescription for Strattera. No breach of Clause 22.2 was ruled.

The Panel noted its rulings above and consequently ruled no breach of Clauses 9.1 and 2.

During its consideration of this case the Panel observed that health professionals were sometimes concerned that pharmaceutical company employees might have direct contact with patients via various service offerings. The Panel considered that, in introducing and describing their service offerings to health professionals, it would be helpful if companies made the position with regard to patient contact abundantly clear at the outset. Whilst companies were familiar with names of third party service providers, health professionals might not be.

Complaint received **18 June 2009**

Case completed **3 August 2009**