

NHS TRUST CHIEF PHARMACIST v LILLY

Nurse consultancy agreement

The chief pharmacist at an NHS trust, complained about Eli Lilly's approach when it contacted one of the trust's ADHD (attention deficit hyperactivity disorder) nurse specialists to request that he/she speak on behalf of Lilly about its product Strattera (atomoxetine hydrochloride) which was indicated in the treatment of ADHD. The nurse in question managed and prescribed for patients.

The complainant noted that, according to an email from Lilly's compliance department the nurse had been contracted for speaking, advisory board, consulting or research collaboration services. The complainant stated that payment for research collaboration of a prescriber was potentially an inducement to prescribe and recommend similar to other health professionals which could lead to disrepute for the complainant's trust with other trusts. The complainant alleged that the arrangement in question was akin to seeding research where a company paid for a product to be prescribed under the auspices of research. The complainant queried whether Lilly had disclosed the payment.

The detailed response from Lilly is given below.

The Panel noted that the complainant had submitted his complaint after seeing the email referred to above. The Panel assumed that the recipient was the person within the trust, nominated by the nurse, to comment on his/her proposed relationship with Lilly before any contracted services were undertaken. The Panel noted Lilly's submission that this increased transparency around any proposed relationship or consultancy agreement. In that regard the Panel considered that it was unfortunate that the document listed the potential interactions with the nurse and not the intended interaction ie one speaking engagement at a clinical meeting. In the Panel's view, this might have led to the complainant's confusion about the nurse's role.

The Panel noted that Lilly had asked the ADHD nurse specialist in question to speak for 40 minutes, with 20 minutes for questions and answers, at a local clinical meeting entitled the Strattera Experience Programme. In that regard the Panel considered that the need for a suitable speaker had been identified and there was no evidence that the choice of the nurse in question to fulfil that role was inappropriate. No breach of the Code was ruled. The Panel noted that because of the confusion within the trust about the nurse's role in relation to his/her relationship with Lilly, the meeting, had been cancelled and thus no consultancy fee had been paid. In that regard there was no fee to disclose and so the Panel ruled no breach of the Code.

The Panel further noted that the nurse had not been contracted to collaborate in research; there was no study proposed which was akin to a seeding study as postulated by the complainant. No breach of the Code was ruled. The Panel noted that a particular clause cited by the complainant defined a non-interventional study of a marketed medicine and in that regard it could not be breached. The Panel further noted that there was no evidence to suggest that the consultancy agreement was offered as an inducement to prescribe Strattera. No breach of the Code was ruled.

A chief pharmacist at an NHS trust, complained about Eli Lilly's approach when it contacted one of the trust's ADHD (attention deficit hyperactivity disorder) nurse specialists to request that he/she speak on behalf of Lilly about its product Strattera (atomoxetine hydrochloride). Strattera was indicated for the treatment of ADHD in children of 6 years and older, in adolescents and in adults as part of a comprehensive treatment programme.

COMPLAINT

The complainant noted that the ADHD nurse specialist had been contracted for speaking, advisory board, consulting or research collaboration services as stated in an email from Lilly's compliance department. The complainant submitted that the nurse managed and prescribed for patients and that if he/she was paid to undertake research in lieu of a direct contracted payment, there was a potential breach of Clause 13.2 as it could be construed as a promotional payment to put someone in a study and therefore prescribe the study medicine. The complainant was concerned that the two were not clearly separated and the arrangement was potentially in breach of Clause 18.1.

The complainant further submitted that under Clause 20, the use of any consultants was sought after the need for research was identified. The complainant alleged that the arrangement in question was the other way round so was construed as an inducement which was akin to seeding research where a company paid for a product to be prescribed under the auspices of research. The complainant did not distinguish between a medical consultant and a specialist nurse and considered that that argument was academic. The complainant stated that payment for research collaboration of a prescriber was potentially an inducement to prescribe and recommend similar to other health professionals which could lead to disrepute for the complainant's trust with other trusts.

The complainant queried whether Lilly had disclosed the payment. A small payment would be seen differently to a significantly larger payment

especially as any kind of gift or hospitality should be reasonable.

The complainant applauded Lilly for notifying the trust of the arrangements and in an attached email cited a number of clauses of the Code.

When writing to Lilly the Authority asked it to respond in relation to Clauses 12.2, 13.2, 18.1, 20.1 and 20.2 of the Code as cited by the complainant.

RESPONSE

Lilly denied any breach of the Code and submitted that based on the complainant's letter and attachments a misunderstanding had occurred. In Lilly's view, some of its documentation might have led to the confusion and it intended to address the matter by slightly amending the notification letter.

Lilly submitted that the nurse specialist was asked, as an appropriate speaker, to speak at a Lilly organised, clinical meeting. The request to the nurse was accompanied by Lilly's required documentation; an annual master service agreement (MSA) detailing key terms governing the relationship which applied to each statement of work entered into between Lilly and the health professional during the term of the MSA and a statement of work detailing the specific work that was to be undertaken by the nurse and the honorarium for this work. Examples of these documents were provided. A signed master service agreement was received by Lilly in April 2014.

As of January 2014, Lilly required that before any health professional undertook contracted services with the company, he/she nominated an individual who Lilly would notify of its intention to work with the relevant health professional. This created transparency of the relationship that was being requested by Lilly and the nominated person to comment on the proposed relationship before any contracted services were undertaken. A copy of a letter of notification was provided.

Lilly noted that the complainant had welcomed the information being sent. The document was referred to in the email chain submitted as: 'Notification of Lilly's Business interaction with ...'. (sent 28 April) Lilly submitted that the first paragraph of the letter listed the potential interactions that the employee might have with Lilly, which included speaking, advisory board, consulting or research collaboration. This letter might have led to the confusion as it did not make entirely clear that the nurse had been solely contracted for one speaking engagement as specified in a statement of work. This document was sent to the nominated individuals in the employee's trust to increase the transparency of all working relationships that Lilly might be seeking to conduct with health professionals over the course of the entire term of the MSA. Whilst the nurse with whom Lilly had contracted was provided with a statement of work (copy provided) detailing the exact arrangements for these contracted services, the nominated individual was not provided with this confidential information, since the contracted services were directly between Lilly and the relevant

health professional. Lilly stated that in order to avoid any future misunderstandings, it intended to clarify in the notification that specific engagements would be as stated in a statement of work between Lilly and the relevant health professional.

An email from Lilly (sent 29 April) provided by the complainant made it clear that the nurse would be speaking at a single meeting with none of the other potential business interactions being part of that request. The meeting was cancelled following the concerns raised by the nominated individual. The nurse did not undertake the speaking engagement and consequently no payment had been or would be made to him/her. Lilly did not have any on-going or any planned contracted services with the nurse.

In the case in question the proposed contract fell under Clause 20.1 of the Code and Lilly denied that any breach had taken place. Lilly noted the clauses cited by the complainant and in that regard it denied that any breach of Clause 18.1 had taken place. Payment for a speaking engagement would be appropriate and fell under Clause 20.1 not 18.1. Lilly denied any breach of Clauses 12.2 and 13.2 which it submitted were not relevant to this case. Since there was no request for any research collaboration Lilly denied any breach of Clauses 13.2, 18.1 and 20. Clause 20.2 was cited and the complainant queried whether Lilly had disclosed payments referred to under this Clause. In this case no payment was made as the speaking engagement was declined. Lilly submitted that it was committed to transparency with regard to financial arrangements with health professionals and disclosed all such payments in accordance with the Code. Payments made to health professionals in relation to contracted services in 2012 and 2013 could be found on its website, www.lilly.co.uk.

In summary, Lilly denied a breach of the Code but it understood how the confusion might have arisen.

PANEL RULING

The Panel noted that the complainant had submitted his complaint after seeing an email from Lilly to inform the recipient (the recipient's name was redacted by the complainant) that the company had contracted the named nurse for 'speaking, advisory board, consulting or research collaboration services'. The Panel assumed that this document had been sent to the recipient as he/she was the person within the trust, nominated by the nurse, to comment on his/her proposed relationship with Lilly before any contracted services were undertaken. The Panel noted Lilly's submission that this increased transparency within a trust around any proposed relationship or consultancy agreement. In that regard the Panel considered that it was unfortunate that the document listed the potential interactions with the nurse but did not state the intended interaction ie one speaking engagement at a clinical meeting. In the Panel's view, this might have led to the complainant's confusion about the nurse's role.

The Panel noted that the nurse in question was an ADHD nurse specialist who had been asked by

Lilly, to speak for 40 minutes, with 20 minutes for questions and answers, at a local clinical meeting entitled the Strattera Experience Programme. In that regard the Panel considered that the need for a suitable speaker had been identified and there was no evidence that the choice of the nurse in question to fulfil that role was inappropriate. No breach of Clause 20.1 was ruled. The Panel noted that because of the confusion within the trust about the nurse's role in relation to his/her relationship with Lilly, the meeting, originally scheduled for June 2014, had been cancelled and thus no consultancy fee had been paid. In that regard there was no fee to disclose and in any event the fee would not have to be disclosed until 2015 and so the Panel ruled no breach of Clause 20.2.

The Panel further noted that the nurse had not been contracted to collaborate in research; there was no study proposed which was akin to a seeding study as postulated by the complainant. No breach of Clause 12.2 was ruled. The Panel noted that Clause 13.2 defined a non-interventional study of a marketed medicine and in that regard it could not be breached. No breach of that clause was ruled. The Panel further noted that there was no evidence to suggest that the consultancy agreement was offered to the nurse as an inducement to prescribe Strattera. No breach of Clause 18.1 was ruled.

Complaint received **2 May 2014**

Case completed **1 July 2014**
