

# ANONYMOUS v CEPHALON

## Qualifications of medical signatory

An anonymous non-contactable complainant who described themselves as an ex-employee of Cephalon UK complained that a medical affairs manager with signatory and approval powers was not a qualified doctor.

The detailed response from Cephalon is given below.

The Panel noted that the 2008 Code which applied at the time in question required that, *inter alia*, promotional material must not be issued unless it had been certified by two signatories one of which had to be a registered medical practitioner. The Code did not require the medical practitioner to be registered in the UK but the Authority advised that proposed medical signatories should be capable of being registered in the UK without the need for additional tests of medical/clinical knowledge. There were no requirements in the Code relating to the actual qualifications of medical signatories. The supplementary information stated that in deciding whether a person could be a nominated signatory account should be taken of product knowledge, relevant experience, both within and outwith the industry, length of service and seniority. In addition, signatories must have an up-to-date detailed knowledge of the Code.

The Panel noted that Cephalon had provided a job description to the recruitment agency to identify suitable candidates for the role of interim medical advisor. The job description made it clear that candidates should be medically qualified with current GMC registration and at least 2 years post registration clinical experience. Cephalon submitted that the person in question had undertaken roles within major UK pharmaceutical companies which in its view would have required GMC registration. Cephalon's standard operating procedure (SOP) required that the final medical signature must be a registered medical practitioner and although the person in question completed training on this SOP he did not advise Cephalon of the position. It was only when Cephalon made checks for recruiting a permanent role that it was discovered that the person in question was not GMC registered.

The Panel noted that in the five months he had worked for Cephalon approximately 45 items had been certified by him. These items were reviewed at that time internally by medical and other experienced Code signatories. Following the departure of the person in question Cephalon

reviewed all the items which had been certified by him and submitted that they were of good quality and compliant with the Code.

The Panel considered that there was the possibility that although not GMC registered the person in question was registered as a medical practitioner in another country. The person in question did not indicate to Cephalon that this was so. The Panel considered that in the initial temporary appointment Cephalon had been badly let down by the recruitment agency. However materials had been certified by someone whom Cephalon could not show was a registered medical practitioner. The requirements of the Code had not been met and thus the Panel ruled a breach of the Code as acknowledged by Cephalon.

The Panel noted that the person in question had been trained on Cephalon's SOPs and had received regular updates on the Code from an external agency. No evidence was provided by the complainant to show that the person in question had not received training. The Panel ruled no breach of the Code.

Taking all the circumstances into account, including the requirement from Cephalon that signatories were GMC registered, the Panel considered that on balance Cephalon had not failed to maintain high standards. No breach of the Code was ruled. The Panel did not consider the circumstances warranted a ruling of a breach of Clause 2 which was used as a sign of particular censure and thus no breach of that clause was ruled.

An anonymous non-contactable complainant who described themselves as an ex-employee of Cephalon UK complained about the qualifications and role of a medical affairs manager previously employed by Cephalon.

The complainant was considered under the Constitution and Procedure of the 2011 edition of the Code and in relation to the requirements of the 2008 Code.

## COMPLAINT

The complainant stated that the medical affairs manager was employed by Cephalon between 2009 and 2010 and during this time he had signatory and approval powers. It later transpired that he actually was not a qualified doctor.

Whilst mistakes could occur, on this occasion it

appeared that Cephalon senior management was negligent in its duty in ensuring that all reasonable checks were made and as such left all employees at risk in terms of compliance with the Code.

The complainant advised that although he had now left Cephalon, the gravity of this situation had compelled him to write to try and ensure that correct procedures were put in place and acted upon to avoid a repeat of this incident.

Cephalon was asked to respond in relation to the requirements of Clauses 2, 9.1, 14.1 and 16.1 of the 2008 Code.

## RESPONSE

Cephalon explained that in September 2009 a job description for a medical advisor was sent from Cephalon UK to a recruitment agency to identify suitable candidates to fill the role for an interim medical advisor. The agency in question was selected due to its particular expertise and specialism in recruiting physicians both for the pharmaceutical industry and for the NHS.

Cephalon drew attention to four key elements highlighted within the job description:

- 1 The overall role purpose was to provide 'comprehensive medical advisor support to the UK affiliate in accordance with local regulations and the Code of Practice'
- 2 A key activity was to 'Input to, review and approve promotional materials to Company, UK legal, and ABPI standards'
- 3 One of the typical outputs was 'Approved promotional materials'
- 4 The technical/professional expertise required of the job holder included that the person was 'Medically qualified with current GMC registration and at least 2 years post-registration clinical experience'.

The role reported directly to the Cephalon UK medical director, who was GMC registered and also the hiring manager.

Cephalon UK received a curriculum vitae (CV) for the individual in question from the agency. The CV referred to BSc in Clinical Science from Imperial College London, a medical degree from Imperial College London and membership of the Royal College of Psychiatrists. The person in question had undertaken a variety of roles in the NHS to the level of senior registrar at prominent UK hospitals. Within the pharmaceutical industry, he had undertaken medical roles within three major UK pharmaceutical companies as a clinical research physician and as a medical adviser/senior medical adviser, roles which would have required GMC registration.

A contract for services as an interim medical advisor was signed between the agency and Cephalon UK and the person in question commenced working at Cephalon in late 2009. The person in question was not employed directly by Cephalon UK at any point, but was an independent medical consultant employed via the agency.

As part of the normal process for training of new staff (including contracted staff) the person in question underwent training on a number of Cephalon UK standard operating procedures (SOPs) which were relevant to the Code, as well as numerous other Cephalon SOPs of broader relevance to his role. The person in question on completion of this training, was monitored using an online compliance system which was common to the entire company. One of these SOPs referred to approval of promotional materials and training on this was completed in 2009. The SOP required that the final medical signature must be a registered medical practitioner, and although the person in question completed the training, he did not advise of his deficiency with respect to this.

The person in question also received regular updates on recent cases and key points arising from those cases via an external agency, which specialised in healthcare compliance and codes of practice. This agency provided an update service specifically for Code signatories which the person in question received regularly during his employment.

Following satisfactory spring performance the person in question was offered permanent employment at Cephalon in 2010 subject to satisfactory pre-employment checks.

As part of the normal process for recruitment of permanent staff, further diligence was undertaken by the HR department including obtaining evidence of previous employment (via references from previous employers), evidence of academic qualifications and GMC registration status. At this point, it was discovered that the person in question was not registered with the GMC. The offer of employment was withdrawn and the person in question's employment as a contractor was terminated immediately.

The person in question had been a final Code signatory during the short time he was employed at Cephalon, and he had signed off approximately 45 promotional items. These were reviewed at that time internally by medical and by other experienced Code signatories at Cephalon.

Cephalon's management was naturally extremely concerned about this lack of GMC registration, and an experienced external consultant pharmaceutical physician with 25 years of experience in the pharmaceutical industry was also employed as a matter of urgency to examine the promotional materials that had been signed by the person in question. The external medical consultant confirmed that these were Code compliant, had

been approved to a high standard and that at no time had the sales force been using non-compliant or misleading promotional materials.

The three Cephalon managers who at that time were involved in the recruitment of the person in question were no longer employed by Cephalon UK and it had been unable to obtain additional information from these individuals before responding to the complaint.

In common with many pharmaceutical companies in the UK, Cephalon was occasionally obliged to employ external contractors to fill short-term vacancies and relied upon third parties to source such staff. Section 10.1 of the contract with the agency indicated that it should 'use its best endeavours to ensure that the consultant [the person in question] possesses the skill, experience, reliability, and integrity necessary to properly provide the consultancy services'.

However, Cephalon acknowledged that it must take responsibility for this deficiency and therefore accepted that high standards at that time were not maintained in breach of Clause 9.1.

With respect to the requirements of Clause 16.1, the person in question was specifically trained on company SOPs relevant to the Code and received regular updates about the Code. The findings of the physician employed to examine the promotional items he approved found them to be of good quality. On this basis, Cephalon did not accept a breach of Clause 16.1.

Cephalon accepted also that at that time an error of omission occurred in that the agency failed to highlight the lack of GMC registration despite the fact that this was an absolute requirement of the job description. Cephalon had subsequently changed its procedures to ensure that the GMC status of any physician employed at the company was checked prior to commencing employment, irrespective of whether the employee in question was permanent or externally-contracted. Cephalon also appreciated the serious nature of this matter, and was aware of the potential implications for certification of promotional materials by inappropriate individuals.

Given its action on discovering the situation Cephalon did not accept the complainant's assertions of mismanagement and did not accept a breach of Clause 2.

In response to a request for further information in relation to Clause 14.1 Cephalon stated that the provisions of Clause 14.1 had not been met with regard to the requirement for final certification by a registered medical practitioner, and Cephalon accepted a breach of this Clause.

In respect of the person in question's registration, Cephalon discovered that he was not GMC registered in spring 2010. In addressing the supplementary question as to whether the person in

question was capable of being registered at that time, the company had undertaken extensive inquiries via the GMC online registration facility, but had not found an individual who was on the register who matched the person in question's name and stated qualifications. Further direct communication with the GMC had also failed to elicit a match given the information the company had available. Cephalon was therefore not able to give a definitive answer to the question in relation to his capability of being GMC registered.

The person in question did not indicate to Cephalon that he was registered in another jurisdiction and the company had had no communication with him since he had stopped working at Cephalon. It had not received any further information relevant to these matters from the recruitment agency in question.

## PANEL RULING

The Panel noted that Clause 14.1 of the 2008 Code which applied at the time in question required that, *inter alia*, promotional material must not be issued unless it had been certified by two signatories one of which had to be a registered medical practitioner. Clause 14.1 also allowed a practising UK registered pharmacist working under the direction of a registered medical practitioner to certify certain material as set out in Clause 14.1. The Code did not require the medical practitioner to be registered in the UK but the Authority advised that proposed medical signatories should be capable of being registered in the UK without the need for additional tests of medical/clinical knowledge. There were no requirements in the Code relating to the actual qualifications of medical signatories. The supplementary information stated that in deciding whether a person could be a nominated signatory account should be taken of product knowledge, relevant experience, both within and outwith the industry, length of service and seniority. In addition, signatories must have an up-to-date detailed knowledge of the Code.

The Panel noted that Cephalon had provided a job description to the recruitment agency to identify suitable candidates for the role of interim medical advisor. The job description made it clear that candidates should be medically qualified with current GMC registration and at least 2 years post registration clinical experience. Cephalon submitted that the person in question had undertaken roles within 3 major UK pharmaceutical companies which in its view would have required GMC registration. Cephalon's SOP required that the final medical signature must be that of a registered medical practitioner and although the person in question completed training on this SOP he did not advise Cephalon of the position. It was only when Cephalon made checks for recruiting the person in question to a permanent role that it was discovered that he was not GMC registered and the offer of employment was withdrawn and the person in question dismissed.

The Panel noted that in the five months he had worked for Cephalon approximately 45 items had been certified by him. These items were reviewed at that time internally by medical and other experienced Code signatories. Following the departure of the person in question Cephalon reviewed all the items which had been certified by him and submitted that they were of good quality and compliant with the Code.

The Panel considered that there was the possibility that although not GMC registered the person in question was registered as a medical practitioner in another country. The person in question did not indicate to Cephalon that this was so. The Panel considered that in the initial temporary appointment Cephalon had been badly let down by the recruitment agency. However materials had been certified by someone whom Cephalon could not show was a registered medical practitioner. The requirements of Clause 14.1 had not been met and thus the Panel ruled a breach of that clause as acknowledged by Cephalon.

In relation to the requirements of Clause 16.1, the Panel noted that the person in question had been trained on Cephalon's SOPs and had received regular updates on the Code from an external agency. No evidence was provided by the complainant to show that the person in question had not received training as required by Clause 16.1. The Panel ruled no breach of that clause.

Taking all the circumstances into account, including the requirement from Cephalon that signatories were GMC registered, the Panel considered that on balance Cephalon had not failed to maintain high standards. No breach of Clause 9.1 was ruled. The Panel did not consider the circumstances warranted a ruling of a breach of Clause 2 which was used as a sign of particular censure and thus no breach of that clause was ruled.

**Complaint received**                      **16 June 2011**

**Case completed**                              **26 July 2011**

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