ANONYMOUS GASTROENTEROLOGY CONSULTANT v ALMIRALL

Free stock allegedly offered as an inducement

An anonymous, non-contactable gastroenterology consultant complained that an Almirall representative had offered a colleague free stock of Constella (linaclotide) as a trial to support a formulary application. The complainant was very much against this type of promotion and considered that his/her department was compromised by the inducement.

The detailed response from Almirall is given below.

The Panel noted that the complainant had provided little to support his/her complaint and had not been party to the interaction in question. As with any complaint, the complainant had the burden of proving his/her complaint on the balance of probabilities; the matter would be judged on the evidence provided by the parties.

The Panel noted that medical representatives had yet to be involved with the promotion of Constella. Healthcare development managers (HDMs) were involved with the product and pre-licence activities had centred around understanding local procedures for providing free stock of medicines. The HDMs were briefed not to discuss linaclotide or to actively solicit free stock. Post-licence, HDMs were similarly instructed not to actively solicit free stock supply of Constella. The Panel further noted that Almirall planned to provide limited free stock of Constella only after it was licensed and before it was launched.

The Panel considered that Almirall's role once it received a request for free stock was not entirely clear. It appeared that free stock would only be supplied once the relevant hospital trust had agreed and presumably followed its own procedures. In this regard it appeared that a formulary application would have had to be submitted before Constella could be supplied. To date, where free stock had been supplied, Constella had been granted provisional formulary approval pending local clinical evaluation. The Panel noted Almirall's submission that free stock was not offered as an incentive to complete a formulary application; the product would only be supplied after a positive formulary assessment (provisional or confirmed).

The Panel could not ask the complainant for more information and so it could not know exactly what had transpired between the Almirall employee and the complainant's colleague or when the interaction took place. Almirall had stated that any discussions about free stock had only arisen post-licence. The Panel did not consider that the complainant had shown, on the balance of probabilities, that his/her colleague had been offered a free supply of Constella as an inducement to submit a formulary application. No breach of the Code was ruled. The Panel thus did not consider that there was any evidence to show that the HDM or the company had failed to maintain high standards. No breaches of the Code were ruled.

The Panel noted its rulings above and ruled no breach of Clause 2.

An anonymous, non-contactable gastroenterology consultant in a named UK area complained that an Almirall Limited representative had offered free stock of Constella (linaclotide).

COMPLAINT

The complainant explained that one of his/her colleagues discussed Constella with an Almirall representative who stated that free stock could be offered as a trial to support a formulary application.

The complainant stated that he/she was very much against this type of promotion and considered that his/her department was compromised by the inducement. The complainant submitted that the representative had stated that this offer had been made across other UK trusts. The complainant alleged a breach of the Code.

When writing to Almirall, the Authority asked it to respond in relation to Clauses 2, 9.1, 15.2 and 18.1 of the Code.

RESPONSE

Almirall stated that in its view, there were two main possibilities: that the complainant objected to the provision of free stock of Constella because he/she considered that it was an inducement to prescribe as defined by Clause 18.1, or that the complainant objected more generally to the provision of free stock because he/she considered this induced clinicians to use new medicines and that this somehow compromised his/her department's normal medicines management processes.

Almirall also considered the possibility that there was something in the language or conduct of Almirall personnel, as reported to the complainant, that suggested that a therapeutic trial was offered on the condition that a formulary application would be made.

Almirall noted that the complainant was not the health professional that met the Almirall

representative but a third party reporting what he/she was told about the meeting. Almirall stated that it had, nonetheless, conducted careful interviews with the limited number of its employees that this meeting could have involved in order to assess the various possibilities.

Almirall explained that Constella was a first-in-class medicine for the symptomatic treatment of irritable bowel syndrome (IBS) with constipation (IBS-C) and was approved by the European Medicines Agency (EMA) in November 2012. Gastroenterologists specialising in IBS had been waiting for this medicine as it was the first one licensed for use in a sometimes difficult to treat subgroup of patients who were frequently referred from primary care. In response to requests for patient supply beginning in the pre-licence period, Almirall had established a process for provision of limited stock, free of charge between product licensing and the planned launch later in 2013.

As of 25 March 2013, no Almirall sales representative had discussed Constella as the team was yet to be deployed on this medicine. One healthcare development manager (HDM) covered the specific area in question and was responsible for ensuring that any supply of Constella requested by consultants occurred with the knowledge of the relevant pharmacy personnel and complied with local governance arrangements. Briefing slides were emailed to the HDMs in advance of a teleconference on 19 November. The presentation made clear the distinction between acceptable pre- and post-licence activity, the reactive nature of the supply process and the need to understand local pharmacy processes in order to comply with them. A copy of the presentation was provided.

A clinician who requested free stock of Constella had to submit a formulary application before supply was agreed within their hospital trust. Thus in all cases, NHS stakeholders were able to accept or reject the medicine based on their assessment of patient need, the product data and consideration of any longer term funding implications. In view of this, it was not clear in what sense the hospital department could have been compromised by supply of Constella as alleged. Furthermore, in cases to date in which free stock had been approved following formulary application, the product had been given only provisional formulary approval, pending evaluation of its real world performance by the clinician involved. Almirall anticipated that the same safeguard would be available within any trust approving the supply. Almirall considered that this significantly increased the opportunity for an accurate assessment of product risk:benefit before full formulary access was granted. Almirall did not understand how, if the shared objective was to benefit patients, working in partnership as it had done to provide free stock could be seen as unhelpful to the NHS.

Almirall submitted that the complainant might have misconstrued the provision of free stock (or the conversation details that were relayed to him/her indirectly) as being offered as an incentive to complete a formulary application. To frame the conversation in this manner would have been inconsistent with the knowledge and experience of the HDM who covered the complainant's area, ie the requesting gastroenterologist could only gain access to the medicine for his/her patients with a positive formulary assessment, hence both parties in the discussion would have known that completing an application was simply a pre-requisite of the usual trust process.

With regard to Clause 18.1, Almirall submitted that free stock of Constella did not constitute a gift and did not benefit or offer any pecuniary advantage to the gastroenterologist or other health professionals who might be involved. Any agreement to supply was in response to clinical demand and with the sole intention of providing patient benefit.

With regard to Clause 15.2, Almirall stated that it had spoken to the relevant HDM regarding his/her interactions with gastroenterologists to date. The HDM denied any portrayal of free stock as an inducement or trial to support a formulary application. To date the HDM team had engaged with a limited number of IBS experts and their respective medicines management colleagues to understand patient referral pathways and formulary application processes in different localities. Any discussions about free stock had arisen only during the post-licence phase (from 27 November 2012) and had been reactive, as per the briefing provided. In terms of representative involvement, only the relevant regional HDM and head office senior medical advisor had discussed the provision of free stock with any clinicians, acting in a strictly non-promotional capacity.

Almirall did not consider that there was any evidence to suggest that the HDM concerned had failed to maintain a high standard or had breached any aspect of the Code. The company suggested that to have separated discussion of free stock from discussion of the local formulary application process would have been incompatible with the requirements of Clause 17.8 ie that the provision of medicines and samples in hospitals must comply with individual hospital requirements.

Almirall did not consider that any evidence had been provided to suggest that high standards had not been maintained (Clause 9.1) and its investigation of the alleged interaction with a gastroenterologist supported this view.

Almirall stated that for the reasons stated above with regard to Clauses 18.1 and 9.1, it did not consider that it had brought discredit upon or reduced confidence in the pharmaceutical industry, either in the reactive provision of free stock *per se* or in the conduct of Almirall personnel involved in the local logistics of provision.

PANEL RULING

The Panel noted that the complainant was anonymous and non-contactable and had provided little information and no documentation to support his/her complaint. The complainant had not been party to the interaction between his/her colleague and the Almirall employee. As with any complaint, the complainant had the burden of proving his/her complaint on the balance of probabilities; the matter would be judged on the evidence provided by the parties.

The Panel noted that medical representatives had yet to be involved with the promotion of Constella. HDMs were already involved with the product; pre-licence activities for the HDMs centred around understanding local procedures for providing free stock of medicines including identifying the key contacts in that process. The HDM briefing slides stated that the HDMs were not to discuss linaclotide and not to actively solicit free stock. The briefing slides referred to requests received by the medical team from clinicians that spontaneously requested free stock. Post-licence, HDMs were similarly instructed not to actively solicit free stock supply of Constella. The Panel further noted that Almirall planned to provide limited free stock of Constella only between product licensing (November 2012) and the product launch in 2013.

The Panel considered that in its response, Allmirall was not entirely clear about its role once it received a request for free stock. However it appeared that free stock would only be supplied once the relevant hospital trust had agreed and presumably followed its own procedures. In this regard it appeared from Almirall's submission that a formulary application would have had to be submitted before Constella could be supplied as free stock. In the two cases to date where free stock had been supplied, Constella had been granted provisional formulary approval pending its clinical evaluation by the clinicians concerned. The Panel noted Almirall's submission that the provision of free stock was not offered as an incentive to complete a formulary application; the product would only be supplied after a positive formulary assessment be that on a provisional or confirmed basis. The Panel further noted Almirall's submission that the provision of free stock significantly increased the opportunity for an accurate assessment of a product before full formulary status was granted.

The Panel noted that as the anonymous complainant was non-contactable it could not ask him/her for more information and so it was impossible to know exactly what had transpired between the Almirall employee (assumed to be the local HDM) and the complainant's colleague or if the interaction took place before or after Constella received its marketing authorization. Almirall had stated that any discussions about free stock had only arisen in the post-licence phase (from 27 November). The Panel did not consider that the complainant had shown, on the balance of probabilities, that his/her colleague had been offered a free supply of Constella as an inducement to submit a formulary application. No breach of Clause 18.1 was ruled. The Panel thus did not consider that there was any evidence to show that the HDM or the company had failed to maintain high standards. No breach of Clauses 9.1 and 15.2 were ruled.

The Panel noted its rulings above and ruled that there had thus been no breach of Clause 2.

Complaint received **13 March 2013**

Case completed **9 April 2013**