# ANONYMOUS GENERAL PRACTITIONER v LILLY

## Alleged promotion of once-weekly Byetta

**An anonymous and uncontactable general practitioner alleged that two different representatives from Eli Lilly had told him that a long-acting version of exenatide (Byetta) would be launched in the UK 'within the next couple of months'. From his own research the complainant found that there had been no such application for a product licence in Europe. The complainant felt that was deliberately misleading and disappointing and that Lilly should advise its representatives not to mislead clinicians in this way.**

**The detailed response from Lilly is given below.**

**The Panel noted that no information had been provided about the Lilly personnel; there was no way of knowing if they were sales representatives or health development managers. Two local sales representatives from central London had, for the purposes of the Diabetes UK Conference, been briefed on exenatide once-weekly for the first and only time on 2 March 2010, the date that the complaint was received by the Authority. Health development managers had been trained on the product in mid February.**

**The Panel noted that the Code prohibited the promotion of a medicine prior to the grant of its marketing authorization.**

**Lilly submitted that its health development managers provided advance notification of the introduction of Byetta once-weekly given that it might significantly affect the budgets of the NHS. The Panel noted that the supplementary information to Clause 3.1 of the Code set out detailed requirements in this regard including that information should be directed to those responsible for making policy decisions on budgets rather than those expected to prescribe. The Panel had no way of knowing the complainant's status in this regard although as a GP it was unlikely that he would direct budgets.**

**Bearing in mind the lack of evidence from the complainant the Panel decided that the complainant had not proved his complaint on the balance of probabilities. No breach was ruled.**

An anonymous and uncontactable general practitioner, complained about comments made by representatives of Eli Lilly and Company Limited about a long acting formulation of Byetta (exenatide).

**COMPLAINT**

The complainant stated that on a couple of occasions recently two different Lilly representatives had told him that a long-acting version of exenatide would be launched in the UK 'within the next couple of months'. Being active in the treatment of diabetes, the complainant carried out his own internet research to find that there had been no such application for a product licence in Europe. The complainant felt that was deliberately misleading and disappointing.

The complainant did not want to get the representatives concerned into trouble but felt that Lilly should advise its representatives not to mislead clinicians in this way.

When writing to Lilly, the Authority asked it to comment in relation to Clauses 3.1 and 7.2 of the Code.

**RESPONSE**

Lilly explained that Byetta was available as either a 5mcg or a 10mcg exenatide per dose pre-filled pen and was indicated for treatment of type 2 diabetes in combination with metformin and/or sulphonylureas in patients who had not achieved adequate glycaemic control on maximally tolerated doses of these oral therapies. Byetta should be initiated at 5mcg twice daily, for a least one month in order to improve tolerability; the dose could then be increased to 10mcg twice daily to further improve glycaemic control.

Exenatide once-weekly was an extended-release medication for type 2 diabetes designed to deliver continuous therapeutic levels of exenatide in a single weekly dose. Both Byetta and exenatide once-weekly were glucagon-like peptide-1 (GLP-1) receptor agonists.

Exenatide once-weekly was not currently licensed for use. The NDA (New Drug Application) was submitted to the FDA in the US in May 2009 and accepted in July 2009. It was based on data from the DURATION (**D**iabetes therapy **U**tilisation: **R**esearching changes in **A**1C, weight, and other factors **T**hrough **I**ntervention with exenatide **On**ce weekly) clinical trial program. A licence application was submitted to the European Medicines Evaluation Agency (EMEA) in March 2010 and it was anticipated that a European licence would be obtained in 2011.

Lilly submitted that its diabetes sales force was required and instructed to promote only licensed products which included Byetta. To this end, no material had been given to sales representatives which referred to exenatide once-weekly and no

general guidance had been issued about responding to requests from health professionals about any aspect of exenatide once-weekly. The latter, Lilly believed was consistent with its objective of ensuring that all promotion of the GLP-1 receptor agonists was focussed upon and restricted to Byetta. This was evidenced by emails between the Byetta brand manager and the ethics and compliance director.

A specific exception to the above occurred in relation to the Diabetes UK Conference in Liverpool (3 to 5 March 2010). In preparation for this, all Lilly staff attending the conference, including Lilly diabetes representatives, were briefed on 2 March 2010 and provided with strict and explicit guidance about responding to any questions or requests from health professionals about exenatide once-weekly. In particular slides 43 and 44 of the briefing presentation clearly addressed the latter and instructed all staff to inform interested delegates, reactively, that exenatide once-weekly was not a licensed product and then to refer any enquiry about exenatide once-weekly to the Lilly clinical research physicians attending the conference or to the Lilly medical information department. Indeed, all other Lilly staff were also instructed not to engage in any conversation about exenatide once-weekly. This briefing was deemed appropriate and necessary given that diabetologists attending this major specialist/academic meeting would have a legitimate interest in medical and scientific information about products such as exenatide once-weekly or other products in development.

Lilly submitted that given the likelihood that exenatide once-weekly might significantly affect the budgets of NHS organisations, Lilly started, in mid February, to train its health development managers (HDMs) to facilitate the advance notification of the introduction of this new medicine. Importantly, the latter did not involve any member of the Lilly diabetes sales force and only involved named HDMs who were briefed, trained and provided with specific information about exenatide once-weekly, in keeping with the requirements of Clause 3.1 and its supplementary information.

Lilly noted that its sales representatives were fully aware of the Code and were required to abide by it as well as Lilly's own internal standard operating procedures which were based on the Code.

In the absence of any specific details about the complainant, such as their name or location of their surgery, and the specific dates and venues when the alleged discussions took place, Lilly had tried to conduct as full an investigation as possible. Lilly had identified all the relevant members of its sales force who promoted Byetta in the complainant's area. It had discussed the allegations with the national sales manager who had confirmed that there had been no sales force briefing about exenatide once-weekly. Lilly therefore did not expect any of its sales representatives to have discussed exenatide once-weekly as alleged. On this basis Lilly did not accept the complainant's allegations. Lilly categorically refuted the complainant's suggestion that Lilly had intentionally misled him.

Two members of the Lilly diabetes sales force who promoted Byetta in the complainant's area supported Lilly's promotional activity at the Diabetes UK Conference in Liverpool. As discussed previously, they, along with all other Lilly staff attending the conference, were specifically briefed on 2 March 2010 and given strict and clear guidance about responding to any requests from health professionals about exenatide once-weekly. This being the first and only such briefing to involve Lilly sales representatives covering the complainant's area, Lilly noted that the date of the briefing coincided with that of the complaint which referred to two, presumably prior, occasions when Clauses 3.1 and 7.2 were allegedly breached by Lilly sales representatives working in the complainant's area.

Lilly therefore refuted the allegation that its sales representatives had promoted exenatide once-weekly prior to the grant of a marketing authorization and deliberately misled the anonymous complainant. Lilly remained confident of the high standard and quality of all Lilly training and briefing materials and rejected the alleged breach of Clauses 3.1 and 7.2.

If the Authority could provide any further specific details regarding these allegations, Lilly would investigate the matter further.

In conclusion, Lilly was cognisant of its responsibilities with respect to the Code and had ensured that the promotional activities of its sales representatives were consistent with this (including, without limitation, Clauses 3.1 and 7.2) and of the highest standard and quality.

**PANEL RULING**

The Panel noted that the complainant was anonymous and non contactable. No information had been provided about the Lilly personnel alleged to have promoted exenatide once-weekly. There was no way of knowing if they were sales representatives or health development managers. Two sales representatives from the complainant's area had, for the purposes of the Diabetes UK Conference, been briefed on exenatide once-weekly for the first and only time on 2 March 2010, the date that the complaint was received by the Authority. Health development managers had been trained on the product in mid February.

The Panel noted that the Clause 3.1 prohibited the promotion of a medicine prior to the grant of its marketing authorization.

Lilly submitted that its health development managers provided advance notification of the introduction of Byetta once-weekly given that it might significantly affect the budgets of the NHS.

The Panel noted that the supplementary information to Clause 3.1 of the Code set out detailed requirements in this regard including that information should be directed to those responsible for making policy decisions on budgets rather than those expected to prescribe. The Panel had no way of knowing the complainant's status in this regard although as a GP it was unlikely that he/she would direct budgets.

Bearing in mind the lack of evidence from the complainant the Panel decided that the complainant had not proved his/her complaint on the balance of probabilities. No breach of Clauses 3.1 and 7.2 was ruled.

During its consideration of this case and on the basis of the documents provided, the Panel queried whether the activities of the health development managers met the supplementary information to Clause 3.1, Advance notification of new products or product changes, particularly that in order to provide information to those responsible for policy decisions on budgets, the likely cost and budgetary implications must be indicated and must be such that they will make significant differences to the likely expenditure of health authorities and trust hospitals and the like. Lilly's statement about the cost of the product was equivocal in that there was a **likelihood** that exenatide once-weekly **might** significantly affect NHS budges (emphasis added) and there was no further details in the materials provided to the Panel. The Panel requested that Lilly be advised of its concerns in this regard.

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| **Complaint received** | **2 March 2010** |
| **Case completed** | **25 March 2010** |