CASE AUTH/1796/2/06 *NO BREACH OF THE CODE*

PRIMARY CARE TRUST HEAD OF PRESCRIBING v NOVO NORDISK

Insulin discontinuation announcement

The head of prescribing at a primary care trust complained about a four page leaflet sent by Novo Nordisk entitled 'Discontinuation Announcement'. Page 1 took the form of a 'Dear Colleague' letter and stated that Novo Nordisk's animal insulin range (Pork Actrapid, Pork Mixtard and Pork Insulatard) would not be available after 31 December 2007. The letter referred readers to page 4 of the leaflet, the back page, which featured a chart of alternative preparations (insulin analogues, human insulins and other animal insulins) from Novo Nordisk and other manufacturers. Prescribing information for the Novo Nordisk insulins was included together with a statement as to where it could be found. The date of preparation of the leaflet was January 2006.

The complainant appreciated the company giving the NHS very early notice of this product withdrawal but was concerned that the first sentence of the letter 'As you are probably aware the vast majority of patients with diabetes who require insulin are now initiated on analogue insulins' might not be true; the sentence had little to do with the reason for the letter. It became clearer why the sentence was included when one noted that in the table of possible alternative preparations from Novo Nordisk on the reverse of the letter insulin analogues appeared at the far left while the 'equivalent' human products were in the centre column. In response to a query the complainant had received a similar table of data from the medical information team. This table compared the different products and highlighted the similarities between the human and animal products and also showed the differences compared to the analogue insulin equivalents.

The complainant considered that it was apparent from the inclusion of the first sentence and the layout of the table that the letter was not merely about the discontinuation of animal insulin but also promoted insulin analogues. This was further apparent as the insulin analogues were not available in 10ml vials but in pen style devices (FlexPen and 3ml Penfill) only. Patients changed to this type of insulin would have to change presentation as well as change insulin type.

The complainant was further concerned that the letter was signed by the managing director of the UK and Ireland. This was not someone who should make unreferenced promotional statements to prescribers without any medical evidence for the assertions.

The Panel noted that the 'Dear Colleague' letter on page 1 began with the sentence 'As you are probably aware the vast majority of patients with diabetes who require insulin are now initiated on analogue insulins'. The Panel noted from sales data provided by Novo Nordisk that the market share of analogue insulins was growing and the human and animal insulin market share was decreasing. The animal insulin market, which represented 2% of the total insulin market, was shrinking by 17% a year. The market share at September 2005 was just over 50% for analogue insulins and about 46% for human insulins; animal insulins took the rest. Given the rate of growth of insulin analogues and their market

share, the Panel did not consider it unreasonable to claim that the vast majority of patients were initiated on such products. In that regard the Panel considered that the opening sentence of the letter was not misleading and could be substantiated. No breach of the Code was ruled.

The Panel considered that the leaflet at issue, as well as serving as a discontinuation notice for Novo Nordisk's animal insulins, also informed the reader of the possible alternatives available either from Novo Nordisk or other manufacturers. The leaflet sought to persuade health professionals to switch patients to one of the Novo Nordisk alternatives. Prescribing information for all of the Novo Nordisk products was included. In the Panel's view it was not unreasonable for the managing director to have signed the letter. The Panel considered that the presentation and format of the leaflet was such that its promotional intent was not disguised. No breach of the Code was ruled.

The Panel noted the complainant's comment about unreferenced promotional claims. The Code did not require all claims to be referenced, only those which referred to published studies. Claims had to be capable of substantiation and that substantiation had to be provided to a health professional on request.

The head of prescribing at a primary care trust complained about a four page leaflet (ref INS/525/1205) which he had received from Novo Nordisk Limited, entitled 'Discontinuation Announcement'. Page 1 took the form of a 'Dear Colleague' letter and stated that Novo Nordisk's animal insulin range (Pork Actrapid, Pork Mixtard and Pork Insulatard) would not be available after 31 December 2007. The letter referred readers to page 4 of the leaflet, the back page, which featured a chart of alternative preparations (insulin analogues, human insulins and other animal insulins) from Novo Nordisk and other manufacturers. Prescribing information for all of the Novo Nordisk insulins referred to in the leaflet was on the inside pages, pages 2 and 3, of the leaflet. The letter directed the reader to where the prescribing information could be found and stated that the date of preparation of the piece was January 2006.

COMPLAINT

The complainant stated that whilst he appreciated the company's efforts to keep the NHS informed about its commercial decisions and also the very early notice of this product withdrawal, he was concerned about some of the content of the letter.

The first sentence of the letter stated 'As you are probably aware the vast majority of patients with diabetes who require insulin are now initiated on analogue insulins'. The complainant was unsure if this was true but more importantly this had little to do with the reason for the letter.

It became clearer why the sentence was included when one considered the table of possible alternative preparations from Novo Nordisk on the reverse of the letter. This table placed the insulin analogues at the far left of the table while the 'equivalent' human products were in the centre column. In response to a query the complainant had received a similar table of data from the medical information team. This table compared the different products and highlighted the similarities between the human and animal products and also showed the differences compared to the analogue insulin equivalents.

The complainant considered that it was apparent from the inclusion of the first sentence and the layout of the table on the reverse that the letter was not merely about the discontinuation of animal insulin but also promoted insulin analogues. This was further apparent as the insulin analogues were not available in 10ml vials but in pen style devices (FlexPen and 3ml Penfill) only. Patients changed to this type of insulin would have to change presentation as well as change insulin type.

The complainant was further concerned that the letter was signed by the managing director of the UK and Ireland. This was not someone who should make unreferenced promotional statements to prescribers without any medical evidence for the assertions.

When writing to Novo Nordisk, the Authority asked it to respond in relation to Clauses 7.2, 7.4 and 7.10 of the Code.

RESPONSE

Novo Nordisk submitted that the letter was carefully worded to communicate news that some people found very emotional, ie the discontinuation of medicines. Based on experience, the company knew a good way to formulate such a letter was to explain the reasoning for its decision, break the news and then to offer health professionals support in the process.

Novo Nordisk decided to discontinue its animal insulin range because of their decline in use and the overall popularity of analogue insulins. It was quite relevant to state this fact. Based on IMS British Pharmaceutical Index data, current animal insulin usage represented less than 2% of the total insulin market and was shrinking by 17% per year whereas the total share of all analogue insulins was growing at more than 210% (year on year data) while the human and animal market share was steadily shrinking at just under –100%. Thus, the analogue market share was growing twice as fast as the human and animal insulin shares were shrinking. This demonstrated that the analogue insulins were taking market share from other insulins as patients were migrating from one to the other but more importantly that new insulin patients were mainly started on analogue insulins.

As analogue insulins had the biggest market share and were growing in market share, it thus made sense to put them first in a table of alternatives, before the other less popular options. In this table it was stated that the suggested alternatives did not all come in vials and that patients would need a change device as well, should they choose to use Novo Nordisk's analogue products. Based on market data disposable pens and cartridges for re-usable pen devices were more popular than vials and syringes and thus put the more popular alternative before the least popular

alternative. Novo Nordisk noted that it had listed competitors' animal insulins.

Novo Nordisk took the announcement of discontinuation of products very seriously. This letter, as all important communications, was signed by the most senior person in the company – the Managing Director for UK and Ireland.

All communication regarding the discontinuation process was developed with the full knowledge of the Department of Health as well as Diabetes UK. Both organisations saw the letter before it was sent out.

This letter was the first communication Novo Nordisk had sent to health professionals regarding the discontinuation of animal insulins and no promotional message was intended in stating the reason for this decision. Furthermore, this letter did not mention any specific brands and the company did not believe the letter to be in breach of Clause 10.1 of the Code.

The information provided in the letter was accurate, balanced and fair. There were no claims or comparisons regarding any product that could be seen as promotional. Novo Nordisk denied a breach of Clause 7.2. The market share information of all analogue insulins (from Novo Nordisk and other companies) could be substantiated by IMS data, in compliance with Clause 7.4 of the Code.

PANEL RULING

As the leaflet had been prepared in January 2006, the provisions of Clauses 7.2, 7.4 and 7.10 in the 2006 Code were considered. Clause 7.2 in the 2006 Code was the same as that in the 2003 Code with regard to the need for claims to be accurate and balanced etc. There were no changes to Clauses 7.4 and 7.10 in the 2006 Code.

The Panel noted that the 'Dear Colleague' letter on page 1 of the leaflet at issue began with the sentence 'As you are probably aware the vast majority of patients with diabetes who require insulin are now initiated on analogue insulins'. The Panel noted from sales data provided by Novo Nordisk that the market share of analogue insulins was growing and the human and animal insulin market share was decreasing. The animal insulin market, which represented 2% of the total insulin market, was shrinking by 17% a year. The market share at September 2005 was just over 50% for analogue insulins and about 46% for human insulins; animal insulins took the rest. Given the rate of growth of insulin analogues and their market share, the Panel did not consider it unreasonable to claim that the vast majority of patients were initiated on such products. In that regard the Panel considered that the opening sentence of the letter was not misleading and could be substantiated. No breach of Clauses 7.2 and 7.4 was ruled.

The Panel considered that the leaflet at issue, as well as serving as a discontinuation notice for Novo Nordisk's animal insulins, also informed the reader of the possible alternatives available either from Novo Nordisk or other manufacturers. The leaflet sought to persuade health professionals to switch patients to one of the Novo Nordisk alternatives. Prescribing information for all of the Novo Nordisk products was included. In the Panel's view it was not unreasonable for the managing director to have signed the letter. The Panel considered that the presentation and format of the leaflet was such that its promotional intent was not disguised. No breach of Clause 10.1 was ruled.

The Panel noted the complainant's comment about unreferenced promotional claims. The Code did not require all claims to be referenced, only those which referred to published studies (Clause 7.6). Claims had to be capable of substantiation and that substantiation had to be provided to a health professional on request.

Complaint received **6 February 2006**

Case completed **15 March 2006**