GENERAL PRACTITIONER v PFIZER

Exubera price information

In Case AUTH/1816/3/06 a general practitioner complained that a website, an advertisement and a 'Dear Doctor' letter relating to Exubera (inhaled human insulin), produced by Pfizer, did not state the product's cost.

The journal advertisement and the 'Dear Doctor' letter both stated in the prescribing information 'price yet to be agreed'. The website stated 'The exact NHS price for inhaled insulin is currently unknown – however the anticipated price range for inhaled insulin is approximately £965-£1,240 per patient per year, depending on dosing requirements'. To not provide the cost of the product was not only misleading, but importantly did not allow the complainant to judge the comparative budgetary impact of Exubera with respect to the insulin products he currently prescribed.

In Case AUTH/1818/3/06 the GP further complained about a letter he had received from Pfizer about Exubera training sessions. The complainant queried whether it was premature to train diabetes care specialists on a product which they might not even be able to afford; in the absence of cost information was the training programme not falsely raising the expectation that this treatment would be affordable and that cost was not a consideration in deciding the relevance of this product regardless of any consideration of its efficacy or otherwise? Not providing cost information was tantamount to misleading doctors.

In relation to both cases the Panel noted that as soon as a marketing authorization had been granted for a medicine a company could promote that medicine. The Panel noted that the prescribing information in the printed material at issue referred to the cost of Exubera and stated that the price had yet to be agreed; the website stated that the cost of treatment per patient per year was anticipated to be approximately £965-£1,240. The Panel considered that in the circumstances such statements regarding the cost of the product were acceptable. No breach of the Code was ruled.

In Case AUTH/1818/3/06 the Panel did not consider that the statements about cost were misleading. No breach of the Code was ruled.

In Case AUTH/1816/3/06 a GP complained by email that a website, an advertisement and a 'Dear Doctor' letter relating to Exubera (inhaled human insulin), and produced by Pfizer Limited, did not state the product's cost.

The journal advertisement (ref EXU428) and the 'Dear Doctor' letter (ref EXU485) both stated in the prescribing information 'price yet to be agreed'. The website stated 'The exact NHS price for inhaled insulin is currently unknown – however the anticipated price range for inhaled insulin is approximately £965-£1,240 per patient per year, depending on dosing requirements'.

In Case AUTH/1818/3/06 the GP also complained about a letter (ref EXU490) sent to him by a manager at Pfizer Limited, about training sessions on Exubera (inhaled human insulin).

COMPLAINT

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The complainant stated that Pfizer had been extensively advertising the impending availability of Exubera but had not provided the cost of the product in the prescribing information, where he would have expected it to be.

This was not only misleading, but importantly did not allow the complainant to judge the comparative budgetary impact of the product with respect to the insulin products he currently prescribed. What was the point of promoting the product if prescibers could not decide whether it was affordable or not?

The complainant said that he had had no joy with respect to his recent enquiries to Pfizer.

When writing to Pfizer the Authority asked it to respond in relation to Clause 4.1 of the Code.

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The complainant stated that the letter informed him that training sessions were now taking place on Exubera. If that was indeed the case was it not somewhat premature to train diabetes care specialists on a product which they might not even be able to afford; in the absence of cost information was the training programme not falsely raising the expectation that this treatment would be affordable and that cost was not a consideration in deciding the relevance of this product regardless of any consideration of its efficacy or otherwise? Why would anyone take the time and effort to learn about this product if cost prevented its use? Surely Pfizer was putting the cart before the horse by promoting the availability of the Exubera support package in the absence of cost information being made available; trainees could ill afford to waste time on training on a potentially unaffordable product. Any relevance of this product had to be decided by a consideration of cost-efficacy or some assessment. Not providing cost information was tantamount to misleading doctors.

When writing to Pfizer the Authority asked it to respond in relation to Clauses 4.1 and 7.2 of the Code.

RESPONSE

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Pfizer explained that a requirement of its European marketing authorization, granted on 24 January 2006, was that it must conduct an educational programme prior to the launch of Exubera. This was to ensure that health professionals involved in the care of diabetics could familiarise themselves with this entirely new way of delivering insulin, including learning about new dosing and monitoring requirements and about those for whom Exubera was

contraindicated or not recommended. This was admittedly an unusual situation and Pfizer was not aware of other products which had had a compulsory educational commitment imposed by the European regulatory authority prior to the product launch.

The consequences of the timing of the educational programme meant that Pfizer had still to agree prices with the Department of Health (DoH) for the various components of the Exubera inhaled insulin system when the advertisements for the education and training programme were published.

Prior to publication, Pfizer sought informal advice from the Authority, which advised that not including a price in the prescribing information was acceptable since the price was truly not known, the medicine was not yet available, Pfizer was being transparent about the educational programme (not promotional) and that there was no attempt to mislead the readers of the advertisement for the programme. In addition the Medicines and Healthcare products Regulatory Agency (MHRA) had pre-vetted all Exubera materials and had approved all materials relating to the educational programme including the website.

Finally it should be noted that all educational material without a price in the prescribing information would be withdrawn immediately prior to the launch and the promotion of Exubera.

Pfizer noted that Exubera was not yet available to prescribe and this was very clearly communicated in the advertisements. These advertisements were for a training programme, not a product. But since Exubera was mentioned by name Pfizer considered it appropriate to include its draft prescribing information even though prices were not yet agreed with the DoH. This contained a summary of important information that a health professional would need to know prior to prescribing Exubera. It was important to note that, unlike a promotional advertisement for a product, no efficacy and safety claims were made in these advertisements. The advertisements clearly invited health professionals to arrange training by contacting the INH Programme Healthcare Team directly (secondary care mailings) or to visit the relevant website (primary care mailings).

Pfizer agreed that the ability to assess the budgetary impact of a new medicine was important. Pfizer had approached budget holders with annual cost guidelines for Exubera of between £965 and £1240. The website above also had a downloadable formulary pack which contained this price banding and all GPs had been directed to this website. It was not clear why the complainant considered that he did not have access to this information. Without knowing more it was impossible to comment as to who in his primary care trust might have been approached by a Pfizer representative and would also have had knowledge of this price banding. It was important to stress that only budget holders were approached prior to the marketing authorization being granted at the end of January 2006.

Pfizer submitted that it had been completely transparent in its communications with health professionals stating very clearly that there was currently no product available and that the price was yet to be established. Pfizer was obliged to educate health professionals and considered it unacceptable to wait until a price had been agreed before commencing this educational programme. Inhaled insulin was an important development in insulin delivery and to delay its introduction would have caused disappointment to many people who had been awaiting its arrival. As stated above, any materials without a price would be withdrawn immediately prior to the launch, which was planned for May. Pfizer therefore failed to see how its advertisements or other activities could have been any more transparent and did not agree that it had either deliberately or accidentally misled health professionals.

Pfizer noted that it was unable to deal with the complainant's comments the he had failed to get information from the company as it did not know who he was. Pfizer had a field-based team of primary care account managers who would certainly have been able to provide this information. In addition, pricing information was available on the website (in the formulary pack, available from 13 February) and the mailings which went to health professionals on the week commencing 20 February, meaning that recipients had immediate access to the information. The price banding was also available from Pfizer's medical information officers who, in calls after 24 February, were instructed to advise GPs of the cost banding given above. Pfizer regretted that the complainant considered he was unable to obtain this information and would be happy to investigate this further, with further details with the complainant's permission.

In summary Pfizer had been careful not to promote Exubera itself, despite having a marketing authorization and had put in place a comprehensive educational programme about which it had alerted health professionals through mailings, advertisements and a website. Pfizer did not accept that, in these unusual circumstances, there had been a breach of Clause 4.2 of the Code and it hoped that it had reassured the Authority that consultations with agreement had taken place with both the MHRA and the Authority before the advertisements for the educational programme were published and the letter was sent.

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Pfizer made an almost identical response to that above but noted in addition that the letter at issue was sent in March to those health professionals with a specialist interest in diabetes (senior hospital doctors in diabetes, diabetes specialist nurses and GPs with a specialist interest), to remind them about the training programme for Exubera.

PANEL RULING

In relation to both cases the Panel noted that as soon as a marketing authorization had been granted for a medicine a company could promote that medicine. Some companies, however, occasionally found themselves in the position of having a marketing authorization but no agreed price. A pragmatic approach had to be taken. The Panel noted that the

prescribing information in the printed material at issue referred to the cost of Exubera and stated that the price had yet to be agreed; the website stated that the cost of treatment per patient per year was anticipated to be approximately £965-£1,240. The Panel considered that in the circumstances such statements regarding the cost of the product were acceptable. No breach of Clause 4.1 was ruled.

In Case AUTH/1818/3/06 the Panel did not consider that the statements about cost were misleading. No breach of Code 7.2 was ruled.

Complaints received:

Case AUTH/1816/3/06	**24 March 2006**
Case AUTH/1818/3/06	**30 March 2006**
Cases completed	**15 May 2006**