GENERAL PRACTITIONER v TAKEDA

Promotion of Prostap

A general practitioner complained about the promotion of Prostap (leuprorelin acetate) at a meeting sponsored by Takeda UK. The complainant alleged that in response to a question about the licensed indication for Prostap being intramuscular in some cases and subcutaneous in others, the speaker stated that it did not matter which route was used. The complainant queried whether that represented promotion outwith the product licence.

The detailed response from Takeda is given below.

The Panel noted that as stated in the introduction to the Constitution and Procedure, a complainant had the burden of proving their complaint on the balance of probabilities. The Panel had to make a decision based on the evidence before it. The Panel noted that the parties' accounts of the question and answer at issue differed; it was difficult to establish where the truth lay. The speaker and chairman had provided consistent accounts of the speaker's answer. The speaker's slides made no reference to any particular route of injection. The Panel considered that the complainant had not established that, on the balance of probabilities, the speaker had promoted Prostap outwith its marketing authorization as alleged. No breaches of the Code were ruled including no breach of Clause 2.

A general practitioner complained about the promotion of Prostap (leuprorelin acetate) at a meeting sponsored by Takeda UK Ltd. Prostap was a luteinising hormone-releasing hormone (LHRH) agonist indicated, *inter alia*, in the treatment of prostate cancer.

COMPLAINT

The complainant noted that at a Takeda-sponsored meeting entitled 'An Update on Prostate Cancer', held in May 2013, a delegate asked the speaker about the licensed indication for Prostap being intramuscular in some cases and subcutaneous in others. The speaker responded that it did not matter which route was used and the Takeda representative made no comment. The complainant queried whether this represented promotion outwith the product licence.

When writing to Takeda, the Authority asked it to respond in relation to Clauses 3.2, 9.1 and 2 of the Code.

RESPONSE

Takeda submitted that it had organised and funded the meeting in question for an audience of GPs and NHS Commissioners. The meeting was organised and attended by two Takeda representatives, chaired by an external consultant and the presentation in question entitled 'A Practice Based Case Study in the Management of LHRH agonist Provision' was given by a health professional acting as a consultant to Takeda. Takeda stated that, given the complainant's concerns, it had asked the speaker, the chairman and the representatives present for their recollection of the question asked and the speaker's subsequent response. All parties agreed that the question was fully replied to in accordance with the product licence. Under the circumstances, the representatives did not consider that any further information was necessary. Both the speaker and the chairman agreed that there was no reason for the representatives to provide any further explanation.

Takeda submitted that the speaker had stated:

> 'The sequence of events was that I was asked about the variance of injection approaches for Prostap. I explained that the studies done on female patients for endometriosis involved a 90 degree angle approach intra muscularly and that the men's study was done with a 45 degree subcutaneous approach and as that is what was done during the trials, that is why there is a difference. I did say that clinically I do not know if it would make a difference, but that "those are the rules".
>
> As I had said "those are the rules", and had already explained what they were and the reasons for the prescribing advice, there was no requirement for the Takeda representative to make any further comment.'

The chairman stated:

> '…the question asked was:
>
> Why is there a difference between how Prostap 3 DCS is administered for men and women?
>
> [The speaker's] reply confirmed that following the studies, they concluded that the chosen licensed indication was subcutaneously for males and intramuscular for females.
>
> [The speaker] further stated that he couldn't comment on whether there was a clinical difference, but emphasized that licensed indications stated should be the route of administration.
>
> In response to your final query, I can see no reason why the representative from Takeda would need to make any further comments in respect to the licensed indication.'

Takeda submitted that both the speaker and chairman confirmed that the speaker's response was in line with the UK licence for Prostap 3 DCS, which was the product formulation referred to. Section 4.2 of the Prostap summary of product characteristics

(SPC) stated that for prostate cancer, the usual recommended dose was 11.25mg presented as a three month depot injection and administered as a single subcutaneous injection at intervals of three months and for endometriosis, the recommended dose was 11.25mg administered as a single intramuscular injection every 3 months for a period of 6 months only.

Takeda submitted that based on the above, the question was replied to within the letter and spirit of the Code; there was no promotion of or intention to promote, the use of Prostap 3 DCS outside its licence. Takeda thus denied a breach of Clause 3.2. Accordingly, Takeda was confident that high standards were maintained at all times and it thus denied breaches of either Clause 9.1 or Clause 2.

FURTHER COMMENTS FROM THE COMPLAINANT

In response to a request from the Panel for comments on Takeda's submission, the complainant stated that in his view, the crucial section of Takeda's response was the statement '[The speaker] …emphasised the licensed indications stated should be the route of administration'. The complainant submitted that his impression of what the speaker had said was the exact opposite and he was thus surprised that the representatives did not intervene.

The complainant stated that he had complained mainly to raise Takeda's awareness of the risks it ran due to its lack of vigilance; he hoped it would be more cognisant of this in the future. The complainant expected that it would not be possible to take the matter further since the only evidence was hearsay.

PANEL RULING

The Panel noted that the parties' accounts of the question and answer at issue differed. It was one party's word against the other. The Panel noted the difficulty in dealing with such complaints; it was difficult to establish where the truth lay and to know exactly what was said by the speaker in response to the delegate's question.

As stated in the introduction to the Constitution and Procedure, a complainant had the burden of proving their complaint on the balance of probabilities. The Panel had to make a decision based on the evidence before it. The speaker and chairman provided consistent accounts of the speaker's answer. The slides used by the speaker did not refer to any particular injection route. The Panel thus considered that the complainant had not established that, on the balance of probabilities, the speaker had promoted Prostap outwith its marketing authorization as alleged. No breach of Clause 3.2 was ruled. The Panel consequently ruled no breach of Clauses 9.1 and 2.

Complaint received **23 May 2013**

Case completed **23 July 2013**