

HOSPITAL CHIEF PHARMACIST/DIRECTOR v SHIRE

Alleged breach of undertaking

A hospital chief pharmacist noted that a paper on taste used by Shire had previously been ruled in breach of the Code (Case AUTH/1825/4/06). Shire was still using the paper to promote Calcichew-D₃ Forte; it was being shown to GP practices to encourage prescribing of Calcichew. It had also been circulated to hospital drug and therapeutic committees to support inclusion in the formulary. The complainant sat on a [named] drug and therapeutics committee and had received a copy of this paper in July.

As the matter related to a potential breach of undertaking, it was taken up by the Director as it was the responsibility of the Authority itself to ensure compliance with undertakings. This accorded with advice previously given by the Code of Practice Appeal Board.

The Panel noted that Case AUTH/1825/4/06 had concerned the presentation of data from Rees and Howe which was a study to compare the acceptability of Calcichew-D₃ Forte with Adcal-D₃. The Panel had been concerned that not enough detail had been given in an advertisement such that readers would not know what it was about Calcichew-D₃ Forte that patients preferred. In that regard the Panel considered that the advertisement was misleading and a breach of the Code had been ruled.

The matter now at issue, Case AUTH/1872/6/06, concerned the use of Rees and Howe by Shire. The Panel considered that by using the actual paper Shire had provided all of the information to recipients such that they would be able to tell why patients preferred Calcichew-D₃ Forte. The representatives' briefing material stated that Rees and Howe was essential in differentiating Calcichew-D₃ Forte from its competitors. It showed that 80% of patients preferred Calcichew-D₃ Forte to Adcal-D₃ when comparing grittiness, chalkiness, ease of chewing, swallowing and stickiness.

The Panel considered that use of Rees and Howe was not a misleading comparison. The Panel did not consider that the use of Rees and Howe represented a breach of the undertaking given in Case AUTH/1825/4/06. No breach of the Code was ruled.

A hospital chief pharmacist noted that on 26 May 2006 it had been ruled that Shire Pharmaceuticals Ltd's paper on taste breached Clauses 7.2 and 7.3 of the Code and was unfair and misleading. The complainant alleged that Shire was still using the paper.

As the matter related to a potential breach of undertaking, it was taken up by the Director as it was the responsibility of the Authority itself to ensure compliance with undertakings. This accorded with advice previously given by the Code of Practice Appeal Board.

COMPLAINT

The complainant noted that Shire was still using the paper to promote Calcichew-D₃ Forte. This paper was being shown to GP practices to encourage prescribing of Calcichew. It had also been circulated to hospital drug and therapeutic committees to support inclusion in the formulary. The complainant sat on a [named] drug and therapeutics committee and had received a copy of this paper in July 2006.

The complainant made this complaint about this unethical behaviour on behalf of all the GPs in a [named] PCT and also on behalf of the [named] drug and therapeutics committee.

When writing to Shire, the Authority asked it to respond in relation to Clauses 2, 9.1 and 22 of the Code in addition to Clauses 7.2 and 7.3 mentioned by the complainant.

RESPONSE

Shire assumed that the complainant was referring to Case AUTH/1825/4/06 which was not about the physical use of reprints of the paper to promote Calcichew-D₃ Forte. It was about claims made in an advertising leaflet, which were referenced to Rees and

Howe (2001), which Shire assumed to be the 'paper on taste'. The paper reported a randomised, controlled crossover trial in which two proprietary preparations of calcium and vitamin D were compared. The publication reported a 'comparison of acceptability' (not 'taste') of the two medicines. The variables studied included patients' perception of tablet taste (assessed on a visual analogue scale, ranging from 'very sweet' to 'very bitter', not 'good' to 'bad') but also perceptions of several other organoleptic properties (again assessed on a visual analogue scale but interpretable as relatively 'good' or 'bad') and overall preference. The Panel noted in Case AUTH/1825/4/06 that it was not unreasonable to make the comparison. The actual ruling stated:

'Overall the Panel considered that the claim at issue 'Chew Calcichew-D₃ Forte for Ten Seconds for a pleasant surprise. In a comparative study, Calcichew-D₃ Forte was preferred over Adcal-D₃ by 80% of patients' was a misleading comparison. Thus the Panel ruled breaches of Clauses 7.2 and 7.3 of the Code.'

In summary Shire did not believe that the Panel had ruled out the use of, reference to or distribution of, reprints of Rees and Howe in Case AUTH/1825/4/06. The complainant's belief was incorrect. Shire therefore submitted that there was no case to answer.

Shire submitted that Rees and Howe reported a randomised controlled trial (grade A evidence) and was published in a peer review journal. The paper was refereed. The Code permitted the unsolicited distribution of this type of publication (Clause 11.1). Shire had not breached the Code by distributing the paper. In this era of evidence based medicine it was surely preferable for the source document to be distributed than for potentially misleading advertisements, based on data derived from it, to be published and distributed instead. Furthermore distribution of published results of randomised, controlled trials was entirely consistent with the requirement set out in the Medicines and Healthcare products Regulatory Agency's booklet on the rules governing advertising which stated that promotional activity must encourage the rational use of medicines: Rees and Howe provided useful insights into factors which might be relevant to patient compliance with long-term treatment and therefore helped prescribers and drug and therapeutics committees to make rational choices about medicines.

Shire noted that the complainant stated that the complaint was made 'about this unethical behaviour on behalf of all the GPs in a [named] PCT and also on behalf of the [named] drug and therapeutic committee'.

Shire submitted that its response above clearly demonstrated that it had not behaved in an unethical manner. Shire hoped that the outcome of this case would be communicated to all the GPs in the [named] PCT and also to all of the members of the [named] drug and therapeutics committee who had expressed concern about this matter via the complainant.

Shire submitted that for the reasons set out above it

did not believe that it had breached the undertaking given in relation to Case AUTH/1825/4/06 and thus had not breached Clause 22.

Shire did not believe that it had failed to maintain high standards and thus had not breached Clause 9.1.

Shire did not believe that its activities in distributing reprints of a peer reviewed publication (as allowed under Clause 11.1 of the Code) had undermined confidence in the pharmaceutical industry or brought discredit upon it and thus Shire had not breached Clause 2.

Shire rejected the assertion that it had breached the Code as alleged and contended that its activities had not been unethical.

Shire provided a copy of extracts from its Cycle Briefing Document dated January 2006, for its representatives. In this document, six peer reviewed publications (including Rees and Howe) were recommended for use by the representatives in their calls on health professionals. These publications would also be used, as opportunity arose, to support formulary applications. Shire could not comment on the individual case, not knowing the identity of the pharmacist and PCT in question.

PANEL RULING

The Panel noted that Case AUTH/1825/4/06 had concerned the presentation of data from Rees and Howe which was a study to compare the acceptability of Calcichew-D₃ Forte compared with Adcal-D₃. The Panel had been concerned that not enough detail had been given in an advertisement such that readers would not know what it was about Calcichew-D₃ Forte that patients preferred. In that regard the Panel considered that the advertisement was misleading and a breach of the Code had been ruled.

The matter now at issue, Case AUTH/1872/6/06, concerned the use of Rees and Howe by Shire. The Panel considered that by using the actual paper Shire had provided all of the information to recipients such that they would be able to tell why patients preferred Calcichew-D₃ Forte. The representatives' briefing material stated that Rees and Howe was essential in differentiating Calcichew-D₃ Forte from the competitors. It showed that 80% of patients preferred Calcichew-D₃ Forte to Adcal-D₃ when comparing grittiness, chalkiness, ease of chewing, swallowing and stickiness.

The Panel considered that use of Rees and Howe was not a misleading comparison. No breach of Clauses 7.2 and 7.3 was ruled.

The Panel did not consider that the use of Rees and Howe represented a breach of the undertaking given in Case AUTH/1825/4/06. No breach of Clauses 2, 9.1 and 22 was ruled.

Complaint received 28 July 2006

Case completed 5 September 2006