PRINCIPAL HOSPITAL PHARMACIST/DIRECTOR v SERVIER

Alleged breach of undertaking

A principal hospital pharmacist alleged that a journal advertisement for Coversyl (perindopril) issued by Servier had been used again despite it having previously been ruled to be in breach of the Code in Case AUTH/1756/9/05.

As the complaint involved an alleged breach of undertaking, it was taken up by the Director as it was the responsibility of the Authority itself to ensure compliance with undertakings.

The Panel noted that, at first glance, the advertisement now at issue looked very similar to that considered in Case AUTH/1756/9/05. There were, however, important differences. The claim previously ruled in breach of the Code had implied that Coversyl monotherapy could reduce the risk of a cardiovascular event. The claim now at issue, however, clearly stated that a reduction in cardiovascular events was seen when Coversyl was used as part of a blood pressure lowering regimen in patients who needed more than one agent to reach blood pressure targets. The Panel thus considered that the advertisement had been revised such that there was no breach of the undertaking previously given. The Panel therefore ruled no breach of the Code.

A principal hospital pharmacist complained about a journal advertisement (ref 06COAD339) for Coversyl (perindopril) issued by Servier Laboratories Ltd, alleging that it had previously been ruled to be in breach of the Code.

As the complainant alleged a breach of undertaking, the complaint was taken up by the Director as it was the responsibility of the Authority itself to ensure compliance with undertakings.

COMPLAINT

The complainant noted that he had previously complained about an identical advertisement and a breach of the Code was ruled (Case AUTH/1756/9/05). The complainant understood that Servier would be required to withdraw the advertisement forthwith.

The complainant was appalled to see that Servier had again used the same misleading advertisement. He considered that this required the most severe censure possible as the company clearly regarded his complaint and the Authority with contempt.

When writing to Servier, the Authority asked it to respond in relation to Clauses 2, 9.1 and 22 of the Code of Practice.

RESPONSE

Servier stated that it treated all complaints, whether from health professionals, industry or directly from the Authority, extremely seriously. It respected the rulings made by the Panel or the Appeal Board and strove to ensure that, when ruled in breach of the Code, it complied with the undertaking and gave assurance that it would take all possible steps to avoid similar breaches of the Code occurring in the future.

In Case AUTH/1756/9/05 it was alleged that a claim in large type face that 'The preliminary results of ASCOT, in addition to EUROPA and PROGRESS, prove that BP [blood pressure] lowering with Coversyl 4-8mg can reduce the risk of a CV [cardiovascular] event' was misleading. It was further stated that 'The PROGRESS study included a patient group who received a combination of perindopril and a diuretic and there was a significant reduction in stroke incidence compared with placebo. However, since there was no arm of the study in which patients received a diuretic alone, it was not possible to ascertain whether it was the diuretic or the drug combination which was responsible for the apparent therapeutic benefit'. In its ruling the Panel considered that the advertisement implied that all three studies, ASCOT, EUROPA and PROGRESS proved that blood pressure lowering with Coversyl (alone) could reduce the risk of a CV event. With regard to PROGRESS, this was not so. The Panel considered that the claim was misleading as alleged and ruled a breach of Clause 7.2 of the Code. In summary, the Panel ruled that the claim in question was misleading because it implied that in the PROGRESS study Coversyl alone reduced the risk of a CV event by lowering blood pressure.

In line with the undertaking signed in October 2005, all Coversyl advertising containing the claim in question was immediately withdrawn from use.

Servier noted that the claims in the Coversyl advertisement found in breach of the Code in October 2005 were very different from the current campaign including the advertisement/claim in question. Key differences included: complete change of copy under the main strapline; removal of mention of EUROPA study from copy; change of strapline; removal of ASCOT, EUROPA and PROGRESS trial logos and removal of claim below Coversyl product logo.

The main strapline 'Coversyl (perindopril) can …… effectively reduce BP and deliver 24-hour BP control' was in line with the Coversyl licensed indication and supporting references.

The copy below the main strapline, that had been completely and carefully reworded, clearly took into account the issue highlighted in Case AUTH/1756/9/05, that was the implication that in the PROGRESS study Coversyl alone reduced the risk of a CV event by lowering blood pressure.

The copy in the current Coversyl advertisement stated 'For patients who need more than one agent to reach BP targets, ASCOT and PROGRESS, two landmark clinical studies, demonstrated that using COVERSYL, as part of a BP lowering regimen achieved clinically relevant reductions in BP, which reduced major

cardiovascular events'. By making it clear at the beginning and re-emphasising again in the middle of the copy that with ASCOT and PROGRESS it was Coversyl in combination that reduced BP which in turn reduced major cardiovascular events, Servier considered that it had fully addressed the issue in Case AUTH/1756/9/05. This, along with the other changes to the Coversyl advertising detailed above, completely removed any implication that in the PROGRESS study treatment with Coversyl alone reduced the risk of a CV event by lowering blood pressure.

Therefore, Servier denied that it had breached its undertaking; the company had maintained high standards and had not bought discredit to, and reduced confidence in, the industry.

PANEL RULING

The Panel considered that an undertaking was an important document. It included an assurance that all possible steps would be taken to avoid similar breaches of the Code in future. It was very important for the reputation of the industry that companies complied with undertakings.

The Panel noted that, at first glance, the advertisement now at issue looked very similar to that considered in Case AUTH/1756/9/05. There were, however, important differences. The claim previously ruled in breach of the Code had implied that Coversyl monotherapy could reduce the risk of a CV event. The claim now at issue, however, clearly stated that a reduction in CV events was seen when Coversyl was used *as part* of a BP lowering regimen in patients who needed *more than one agent* to reach BP targets. The Panel thus considered that the advertisement had been revised such that there was no breach of the undertaking previously given. The Panel therefore ruled no breach of Clause 22. It thus followed that there was no breach of Clauses 9.1 and 2.

Complaint received **27 June 2006**

Case completed **16 August 2006**