CASE AUTH/2211/3/09

GENERAL PRACTITIONER v BOEHRINGER INGELHEIM

Micardis and Micardis Plus journal advertisement

A general practitioner complained about a journal advertisement for Micardis (telmisartan) and Micardis Plus (telmisartan and hydrochlorothiazide) issued by Boehringer Ingelheim which appeared in Prescriber. Telmisartan was an angiotensin II antagonist (AIIA) and hydrochlorothiazide was a diuretic. The advertisement featured a photograph of a man apparently rowing a canoe-like boat on a rough sea. The headline read 'You can't know what will happen tomorrow …'. Then, beneath the photograph the headline continued '… but with hypertension, you do have the POWER to be prepared for it …'. Beneath the claim were the product logos for Micardis and Micardis Plus.

The complainant alleged that the claim 'You can't know what will happen tomorrow … but with hypertension, you do have the POWER to be prepared for it … Micardis and Micardis Plus' was misleading, exaggerated and demonstrated an irresponsible approach to the promotion of prescription only medicines.

Micardis and Micardis Plus were solely indicated for the treatment of essential hypertension in adults. In contrast other medicines in the same class, such as candesartan, were additionally, indicated for the treatment of heart failure and left ventricular systolic dysfunction, a recognised potential future cardiovascular outcome associated with uncontrolled hypertension.

Readers, however, would reasonably assume from the reference in the claim to unspecified future events, that Micardis and Micardis Plus not only treated hypertension, but could also prevent/reduce the future occurrence of all potential events associated with essential hypertension.

This claim referred to an unqualified generalisation that could not be substantiated

The detailed response from Boehringer Ingelheim is given below.

The Panel noted that both Micardis and Micardis Plus were indicated solely for the treatment of essential hypertension. The Panel noted Boehringer Ingelheim's submission that the goal of antihypertensive therapy was the eventual reduction in cardiovascular morbidity and mortality. The summary of product characteristics (SPC) for each product, however, stated that the effects of the medicine on mortality and cardiovascular morbidity were currently unknown.

The Panel considered that the claim 'You can't know what will happen tomorrow … but with hypertension, you do have the POWER to be prepared for it …' implied that Micardis and Micardis Plus had some beneficial effects on the long-term consequences of hypertension ie cardiovascular morbidity and mortality. 'You can't know what will happen tomorrow …' implied some event other than continuing hypertension and the second half of the claim implied efficacy in that regard. The Panel considered, however, that such an implication was misleading and inconsistent with the SPCs. The Panel considered that the claim was exaggerated and could not be substantiated. Breaches of the Code were ruled.

A general practitioner complained about a journal advertisement for Micardis (telmisartan) and Micardis Plus (telmisartan and hydrochlorothiazide) (ref MIC2508d) issued by Boehringer Ingelheim Limited which appeared in Prescriber, 19 February. Telmisartan was an angiotensin II antagonist and hydrochlorothiazide was a diuretic. The advertisement featured a photograph of a man apparently rowing a canoe-like boat on a rough sea. The headline read 'You can't know what will happen tomorrow…'. Then, beneath the photograph the headline continued '… but with hypertension, you do have the POWER to be prepared for it…'. Beneath the claim were the product logos for Micardis and Micardis Plus.

COMPLAINT

The complainant alleged that the claim 'You can't know what will happen tomorrow ….but with hypertension, you do have the POWER to be prepared for it…Micardis and Micardis Plus' was misleading and exaggerated; it demonstrated an irresponsible approach to the promotion of prescription only medicines.

Micardis and Micardis Plus were solely indicated for the treatment of essential hypertension in adults. In contrast other medicines in the same class, such as candesartan, were additionally, indicated for the treatment of heart failure and left ventricular systolic dysfunction, a recognised potential future cardiovascular outcome associated with uncontrolled hypertension.

The reference in the claim to unspecified future events, presumably those relating to cardiovascular morbidity and mortality or health-outcome events such as hospitalisation, in

relation to the power to be prepared for these events invited readers to reasonably surmise that Micardis and Micardis Plus were not only efficacious in treating hypertension, but by virtue of their effectiveness/potency, they could also prevent/reduce the future occurrence of all potential events associated with essential hypertension which included mortality, heart failure, stroke, acute coronary syndromes, health-outcome events amongst others.

When writing to Boehringer Ingelheim the Authority asked it to respond in relation to Clauses 3.2, 7.2, 7.4 and 7.10 of the Code.

RESPONSE

Boehringer Ingelheim considered that the claim 'You can't know what will happen tomorrow …but with hypertension, you do have the power to be prepared for it' promoted Micardis and Micardis Plus in a manner consistent with their marketing authorizations in line with Clause 3.2.

The context of the claim was entirely clear and was the condition for which Micardis and Micardis Plus were both licensed: '…but with **hypertension**, you do have the power…' (emphasis added) and Boehringer Ingelheim did not consider that the claim was misleading or in breach of Clauses 3.2 and 7.2. There was no mention of unspecified future events in the advertisement.

The claim referred to treating hypertension effectively now and in the future and, in the context of the current objectives of therapy, Boehringer Ingelheim considered that effective, 24 hour control of blood pressure in hypertension was entirely consistent with this. The advertisement made no claims with regard to the reduction, avoidance of, or any other effect on, future events.

Boehringer Ingelheim did not consider that the advertisement contained a claim that was 'an unqualified generalisation that could not be substantiated' as alleged. The claim was not exaggerated or generalised since it referred to 'hypertension' and in terms of substantiation, in line with Clauses 7.4 and 7.10, there was a large body of evidence demonstrating the efficacy ('power') of Micardis in the treatment of hypertension eg in comparison with other angiotensin II antagonists (Lacourière *et al* 2004, Smith *et al* 2003) or ACE inhibitors (Williams *et al* 2009), and MicardisPlus in comparison with valsartan/hydrochlorothiazide (White *et al* 2006).

It was widely accepted that the goal of hypertension treatment was not simply the reduction of hypertension in and of itself, but the eventual reduction of cardiovascular morbidity and mortality as indicated within various UK clinical guidelines:

- National Institute for Health and Clinical Excellence (NICE) guidelines for the 'Management of hypertension in adults in primary care'

  'Hypertension is a major but modifiable contributory factor in cardiovascular disease (CVD) such as stroke and coronary heart disease (CHD). The object of this guideline is to decrease cardiovascular morbidity and mortality resulting from these diseases.'

- Joint British Societies' Guidelines on 'Prevention of Cardiovascular disease in Clinical Practice'.

  '… total CVD risk management is emphasised in order to maximise CVD risk reduction, of which lowering blood pressure is one important component. Data from many randomised clinical trials provide compelling evidence of the effectiveness of antihypertensive therapy at reducing the risk of CVD. A reduction in blood pressure by an average of 12/6 mmHg can be expected to reduce stroke by 40% and CHD by 20%.'

In summary, Boehringer Ingelheim considered that the claim in question was clearly specific to hypertension, and that the claimed 'power' for Micardis and Micardis Plus in the treatment of hypertension could be substantiated. Boehringer Ingelheim, therefore, did not consider that the claim was misleading, or exaggerated or that it demonstrated an irresponsible approach to the promotion of prescription only medicines as alleged.

PANEL RULING

The Panel noted that both Micardis and Micardis Plus were indicated solely for the treatment of essential hypertension. The Panel noted Boehringer Ingelheim's submission that the goal of antihypertensive therapy was the eventual reduction in cardiovascular morbidity and mortality. Section 5.1, Pharmacodynamic properties, of the summary of product characteristics (SPC) for each product, however, stated that the effects of the medicine on mortality and cardiovascular morbidity were currently unknown.

The Panel considered that the claim 'You can't know what will happen tomorrow … but with hypertension, you do have the POWER to be prepared for it …' implied that Micardis and Micardis Plus had some beneficial effects on the long-term consequences of hypertension ie cardiovascular morbidity and mortality. 'You can't know what will happen tomorrow …' implied some event other than continuing hypertension and the second half of the claim implied efficacy in that regard. The Panel considered, however, that such an implication was misleading and

inconsistent with the particulars listed in the SPCs. Breaches of Clauses 3.2 and 7.2 were ruled. The data supplied by Boehringer Ingelheim in support of the claim demonstrated the hypertensive efficacy of Micardis and Micardis Plus; the studies did not set out to investigate any cardio-protective effect. The Panel considered that the claim was exaggerated and could not be substantiated. Breaches of Clauses 7.10 and 7.4 were ruled.

Complaint received **2 March 2009**

Case completed **30 March 2009**