

GENERAL PRACTITIONER v BAYER

Avelox leavepiece

A general practitioner complained about the front cover of an Avelox (moxifloxacin) leavepiece, issued by Bayer, which stated 'In chest infections, when your first reaction is concern, your first choice should be Avelox'. The complainant was extremely concerned about the message given; obviously Avelox, as a newly developed antibiotic, should not be used in first line therapy. She alleged that the message was misleading.

The Panel noted that the claim advocated the use of Avelox in the treatment of chest infections which caused concern. In the Panel's view such chest infections would include severe cases of community acquired pneumonia for which Avelox was not licensed. The Panel further noted that the Avelox summary of product characteristics (SPC) did not categorically state that the antibiotic should not be used first line although it did state that consideration should be given to official guidance on the appropriate use of antibacterial agents. Thus whilst the claim 'Your first choice should be Avelox' was not inconsistent with the particulars listed in the SPC it implied that Avelox was the first choice ie it was the only first choice. The Panel considered that the claim was misleading and a breach of the Code was ruled.

A general practitioner complained about a leavepiece (ref 6AVEL53) for Avelox (moxifloxacin) issued by Bayer plc, Pharmaceutical Division.

COMPLAINT

The complainant noted that the front cover stated 'In chest infections, when your first reaction is concern, your first choice should be Avelox'. She was extremely concerned about the message that was being given; obviously Avelox, as a newly developed antibiotic, should not be used in first line therapy. She considered that the message given by the advertisement was quite misleading.

When writing to Bayer, the Authority asked it to respond in relation to Clause 7.2 of the Code.

RESPONSE

Bayer stated that the leavepiece was given to primary

care health professionals by its representatives. Bayer considered the claim at issue was consistent with the marketing authorization. Avelox was a fluoroquinolone antibiotic, launched in the UK at the end of March 2003. It was licensed for the treatment of acute exacerbations of chronic bronchitis, community acquired pneumonia (except severe cases) and acute bacterial sinusitis (adequately diagnosed).

There was no specification within the marketing authorization as to where Avelox should be positioned in the treatment of chest infections.

Bayer considered that Avelox was promoted in a clinically appropriate manner; the company had taken great care to ensure that all advertising relating to Avelox was accurate, fair and reflected the evidence clearly.

Bayer did not believe that the claim 'In chest infections, when your first reaction is concern, your first choice should be Avelox' was in breach of Clause 7.2 of the Code.

PANEL RULING

The Panel noted that the claim advocated the use of Avelox in the treatment of chest infections which caused concern. In the Panel's view such chest infections would include severe cases of community acquired pneumonia for which Avelox was not licensed. The Panel further noted that the Avelox summary of product characteristics (SPC) did not categorically state that the antibiotic should not be used first line although it did state that consideration should be given to official guidance on the appropriate use of antibacterial agents. Thus whilst the claim 'Your first choice should be Avelox' was not inconsistent with the particulars listed in the SPC it implied that Avelox was the first choice ie it was the only first choice. The Panel considered that the claim was misleading. A breach of Clause 7.2 was ruled.

Complaint received 4 January 2007

Case completed 2 February 2007