CASE AUTH/2293/1/10

VOLUNTARY ADMISSION BY FERRING

Pentasa abbreviated advertisement

Ferring voluntarily admitted that a Pentasa (mesalazine) abbreviated advertisement published in the programme for Gastro 2009 breached the Code. The advertisement had been placed by colleagues in global marketing Switzerland, who failed to put it through the UK approval procedure. This omission was regretted and steps were being undertaken to emphasise the need for UK approvals.

Ferring acknowledged that the claim, 'the power of five in ulcerative colitis', did not adequately describe the approved UK indications for Pentasa. The UK licensed indication was restricted to mild to moderate ulcerative colitis and the advertisement should have stated this to avoid possible breaches of the Code.

Ferring acknowledged that the adverse event statement was not in line with the Code.

Ferring submitted that 'excellent' in the claim 'Celebrate PODIUM – a study demonstrating excellent clinical efficacy' was in breach because it was ambiguous and gave an exaggerated impression of Pentasa's properties which could not be substantiated.

The action to be taken by the Authority in relation to a voluntary admission was set out in its Constitution and Procedure which stated, *inter alia*, that the Director should treat an admission as a complaint if it related to a serious breach. As failure to certify promotional material and promotion inconsistent with the summary of product characteristics (SPC) were involved, which were serious matters, the Director decided that the admission must be treated as a complaint.

The detailed response from Ferring is given below.

The Panel noted that it was an established principle under the Code that UK companies were responsible for the acts and omissions of their overseas affiliates that came within the scope of the Code. The Panel noted that the UK company had made it clear to global marketing in Switzerland that the advertisement needed to comply with the UK Code including the requirement for certification. Unfortunately this had not happened.

The Panel noted that the advertisement was about the Pentasa range of products. Pentasa enema could be used to treat ulcerative colitis in the distal colon and rectum, and Pentasa tablets could be used to maintain remission in ulcerative colitis otherwise the Pentasa range was indicated for the treatment of mild to moderate ulcerative colitis. The unqualified reference to 'ulcerative colitis' in the advertisement was thus inconsistent with the Pentasa SPCs and misleading in that regard. The Panel ruled breaches of the Code as acknowledged by Ferring.

The Panel ruled that the statement regarding adverse event reporting did not use the obligatory text and was in breach of the Code as acknowledged by Ferring.

The Panel considered that the unqualified claim 'excellent clinical efficacy' was ambiguous and gave an exaggerated impression of Pentasa which could not be substantiated. Breaches of the Code were ruled as acknowledged by Ferring.

The Panel noted that material that had not been certified had been used in the UK. The Panel noted its rulings above of breaches of the Code. The Panel considered that high standards had not been maintained and a breach of the Code was ruled. The Panel did not consider that the circumstances warranted a ruling of a breach of Clause 2 which was a sign of particular censure and reserved for such use.

VOLUNTARY ADMISSION

Ferring Pharmaceuticals Ltd voluntarily admitted that a Pentasa (mesalazine) abbreviated advertisement (ref H53261 UEGW A5 Pentasa v4. indd 1) was in breach of several clauses of the Code. The advertisement had appeared in the programme for Gastro 2009, an independent gastroenterology conference held in London, 21-25 November 2009. The programme was intended for health professionals. Ferring UK became aware of the advertisement in December.

Ferring explained that the advertisement had been placed by colleagues from global marketing in Ferring's Swiss headquarters, who failed to put it through the UK approval procedure. This omission was regretted and steps were being undertaken to emphasise the need for UK approvals of all items where required.

Ferring submitted that the heading, 'the power of five in ulcerative colitis', was an international strapline used in a number of markets outside the UK. Ferring acknowledged that 'ulcerative colitis' did not adequately describe the approved UK indications for Pentasa. In the UK, the licensed indication was restricted to mild to moderate ulcerative colitis and had the advertisement been subject to UK approval, the heading would have

been modified to include the term 'mild to moderate' to avoid possible breaches of Clauses 3.2 and 7.2.

With regard to the adverse event statement Ferring acknowledged that the final sentence, 'Adverse events should also be reported to Ferring Pharmaceuticals Ltd' was omitted in breach of Clause 5.6.

Ferring submitted that the 'excellent' in the claim 'Celebrate PODIUM – a study demonstrating excellent clinical efficacy', which appeared beneath the product logo, was in breach of Clauses 7.2, 7.4 and 7.10 because it was ambiguous and gave an exaggerated impression of Pentasa's properties which could not be substantiated.

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The action to be taken by the Authority in relation to a voluntary admission was set out in Paragraph 5.4 of the Constitution and Procedure which stated, *inter alia*, that the Director should treat an admission as a complaint if it related to a serious breach. As failure to certify promotional material and promotion inconsistent with the summary of product characteristics (SPC) were involved, which were serious matters, the Director decided that the admission must be treated as a complaint. When writing to Ferring, the Authority asked it to respond in relation to Clauses 2, 3.2, 5.6, 7.2, 7.4, 7.10 and 9.1 of the Code.

RESPONSE

Ferring submitted that in July 2009, Ferring global marketing asked for its advice on an early draft of the advertisement which Ferring global had prepared in collaboration with a UK advertising agency. Ferring UK advised that the draft required modification to comply with UK requirements and that the updated advertisement would be subject to UK sign-off. The draft version of the advertisement was sent to the Gastro 2009 committee as a 'place holder' by the advertising agency. A change in personnel at the agency and a lapse in handover procedures meant that this particular item was not tracked appropriately. As a result, the original, draft version of the advertisement was printed in the Gastro 2009 programme. No final certification or go-ahead for this item was given by Ferring UK.

Ferring did not believe that there had been a breach of Clause 2, which related to promotional activities or materials that brought discredit upon, or reduced confidence in, the pharmaceutical industry, either by positive action or inadequate action. Ferring noted that a breach of Clause 2 denoted particular censure and did not believe that the circumstances surrounding this event related in type or scale to the examples of activities which could lead to a breach of this clause.

Ferring believed that the advertisement might be in breach of Clause 3.2 since 'ulcerative colitis', in the international strapline 'the power of five in ulcerative colitis', might not adequately describe the approved UK indications for Pentasa. In the UK, Pentasa tablets were indicated for the treatment of mild to moderate exacerbations of ulcerative colitis and for the maintenance of remission of ulcerative colitis. Pentasa sachets were indicated for mild to moderate ulcerative colitis. In addition the Pentasa enema was indicated for the treatment of ulcerative colitis affecting the distal colon and rectum.

In 2008, during inter-company communication with Shire Pharmaceuticals Ltd about an item promoting Pentasa sachets, Ferring UK agreed not to use 'ulcerative colitis' without the clarification of 'mild to moderate'. In the UK, Ferring had taken a conservative approach to the interpretation of these indications and promoted Pentasa for use in mild to moderate ulcerative colitis. If the advertisement now at issue had been subject to UK approval the heading would have been modified to include the term 'mild to moderate' to avoid a possible breach of Clause 3.2. 'The power of five in ulcerative colitis' was used outside the UK and was intended to refer to the Pentasa range of products and not solely to the sachets. Ferring acknowledged that 'ulcerative colitis' might not be considered to appropriately describe the approved indications in the UK for Pentasa. However, the Pentasa range was not restricted to use in only mild to moderate ulcerative colitis. Pentasa tablets were additionally indicated '… for the maintenance of remission of ulcerative colitis', and Pentasa enema was indicated for the treatment of ulcerative colitis affecting the distal colon and rectum.

Ferring acknowledged that the advertisement was in breach of Clause 5.6 as the statement regarding adverse event reporting omitted the final sentence, 'Adverse events should also be reported to Ferring Pharmaceuticals Ltd'.

Ferring believed that the advertisement might be in breach of Clauses 7.2, 7.4 and 7.10 because the claim 'Celebrate PODIUM – a study demonstrating excellent clinical efficacy' was ambiguous and might give an exaggerated impression of the properties of Pentasa. 'Excellent' might be considered to imply a special benefit for Pentasa over other forms of mesalazine, which could not be substantiated.

Ferring believed that this matter was in breach of Clause 9.1; a failure in the system that resulted in the publication of an advertisement that had not been appropriately approved meant that high standards were not maintained. Ferring endeavoured to consistently maintain high standards and regretted this failing.

Ferring stated that it currently used a hard copy sign-off system in the UK. A number of recent product launches had put increased pressure on that system and towards the end of 2009 Ferring decided to introduce an electronic sign-off system in the first quarter of 2010 to further enhance its

sign-off process. Ferring believed that the introduction of this new system would help to reduce the chance of a recurrence of a similar incident.

In addition, Ferring UK had agreed the following actions with its Swiss colleagues:

- The global product manager responsible for the advertisement had been reminded of the importance of following the relevant standard operating procedure (SOP), which was, regrettably, not implemented correctly on this particular occasion.
- Ferring global would review the SOP to see if it needed to be updated.
- All relevant staff in global marketing had been made aware and briefed in detail of the importance of following the SOP.
- There was a plan to ensure all relevant employees had documented evidence of training with regards to this SOP.

PANEL RULING

The Panel noted that it was an established principle under the Code that UK companies were responsible for the acts and omissions of their overseas affiliates that came within the scope of the Code. The Panel noted that the UK company had made it clear to global marketing in Switzerland that the advertisement needed to comply with the UK Code including the requirement for certification. Unfortunately this had not happened.

The Panel noted that the advertisement was about the Pentasa range of products. Pentasa enema could be used to treat ulcerative colitis in the distal colon and rectum, and Pentasa tablets could be used to maintain remission in ulcerative colitis otherwise the Pentasa range was indicated for the treatment of mild to moderate ulcerative colitis. The unqualified reference to 'ulcerative colitis' in the advertisement was thus inconsistent with the indication in the Pentasa SPCs and misleading in that regard. The Panel ruled breaches of Clauses 3.2 and 7.2 as acknowledged by Ferring.

The Panel noted that the statement regarding adverse event reporting read 'Adverse events should be reported. Information about adverse event reporting can be found at www.yellowcard.gov.uk'. The obligatory text as stated in Clause 5.6 was 'Adverse events should be reported. Reporting forms and information can be found at www.yellowcard.gov.uk. Adverse events should also be reported to [relevant pharmaceutical company]'. The Panel considered that the failure to use the obligatory text was in breach of Clause 5.6 as acknowledged by Ferring. A breach of Clause 5.6 was thus ruled.

The Panel considered that the unqualified claim 'excellent clinical efficacy' was ambiguous and gave an exaggerated impression of Pentasa which could not be substantiated. Breaches of Clauses 7.2, 7.4 and 7.10 were ruled as acknowledged by Ferring.

The Panel noted that material that had not been certified had been used in the UK. The Panel noted its rulings above of breaches of the Code. The Panel considered that high standards had not been maintained and a breach of Clause 9.1 was ruled. The Panel did not consider that the circumstances warranted a ruling of a breach of Clause 2 which was a sign of particular censure and reserved for such use.

Proceedings commenced	**11 January 2010**
Case completed	**24 February 2010**