CASE AUTH/2299/2/10

# SHIRE v FERRING

## Promotion of Pentasa

**Shire complained about the promotion of Pentasa (mesalazine) by Ferring. The items at issue were a 'power of five' booklet, an A4 sheet and an advertisement which were produced by Ferring Global solely for the Gastro 2009 Congress held in the UK in November 2009 and were no longer in use. Shire supplied Mezavant XL (mesalazine).**

**The detailed response from Ferring is given below.**

**Page 5 headed of the booklet headed'… UC remission rates in active disease' detailed the results of Marteau *et al* (2005) and featured a bar chart which showed improved remission rates with Pentasa sachets plus Pentasa enema vs Pentasa sachets plus placebo enema. Shire alleged that the claims 'Nearly 50% improvement in remission rate by adding Pentasa 1g enema' and 'Near normal mean quality of life achieved by 8 weeks and faster using Pentasa sachet + enema combination', did not represent the data and were unclear and misleading.**

**The Panel noted that the claim 'Nearly 50% improvement in remission rate by adding Pentasa 1g enema' was below a bar chart which showed a remission rate of 43% in patients treated with oral Pentasa plus placebo enema vs a 64% remission rate for those treated with oral Pentasa plus Pentasa enema. In that regard the Panel considered that it was clear that the claim meant that half as many patients again benefitted from treatment with Pentasa enema compared with those receiving a placebo enema. The Panel did not consider that the claim, in the context in which it appeared, was misleading as alleged. No breach of the Code was ruled.**

**The claim 'Near normal mean quality of life achieved by 8 weeks and faster using Pentasa sachet + enema combination' was referenced to Currie *et al* (2007). The authors stated that at eight weeks both arms of Marteau *et al* had, on average, almost normal quality of life compared to the UK standard population. The authors did not quantify the normal quality of life in the UK standard population. Quality of life was measured using the EQ-5D measure which had a range of zero (worst possible health state) to 1 (perfect health). The Panel could find no evidence that the 'normal goal' was set as 1 as submitted by Shire. The Panel noted Ferring's submission that the EQ-5D value found for the UK standard population was 0.86.**

**The Panel noted that Shire's complaint about the claim 'Near normal mean quality of life achieved by 8 weeks and faster using Pentasa sachet + enema combination' was based on its belief that a normal quality of life was an EQ-5D score of 1. In that regard Shire had noted that the Pentasa enema treatment group scored only 0.921 at 4 weeks and 0.922 at 8 weeks. Both scores were more than 0.03 less than 1; a change of 0.03 units in the EQ-5D score was regarded as a clinically meaningful change in health status. Given, however Ferring's submission that the EQ-5D value for the UK standard population was 0.86, the Panel noted that the treatment group had exceeded that at both 4 and 8 weeks. The Panel thus did not consider that the claim was misleading as alleged. No breach of the Code was ruled.**

**In relation to page 7 headed 'Pentasa once daily', Shire alleged that the sub-heading 'All Pentasa preparations are approved for once daily use' was inaccurate. The prescribing information stated that for sachets and tablets when used for active disease the medicine was to be taken between 2 and 4 times a day. Maintenance treatment for tablets and sachets was once daily. Enemas and suppositories were to be used once daily.**

**The Panel noted that the page was headed 'Pentasa once daily' and sub-headed 'All Pentasa presentations are approved for once daily use'. These claims were qualified in the bullet points below and in that regard Ferring, in inter-company company dialogue, stated that adequate clarification had been given such that there was no breach of the Code. The Panel noted that claims in promotional material must be capable of standing alone as regards accuracy etc. In general claims should not be qualified by the use of footnotes and the like.**

**The Panel considered that the claims 'All Pentasa presentations are approved for once daily use' beneath the heading 'Pentasa once daily' were misleading as alleged. A breach of the Code was ruled.**

**Shire noted that the A4 sheet 'Worldwide markets where Pentasa is available for the treatment of Crohn's disease; listed the countries where Pentasa was licensed for both active and maintenance treatment of Crohn's disease. The UK SPC for Pentasa did not include the Crohn's disease indication. Prescribing information had not been included.**

**Shire referred to the supplementary information to the Code which included:**

- **'promotional material for a medicine or indication that does not have a UK marketing authorization must be clearly and prominently labelled to that effect'**
- **'… it must be stated that registration conditions differ from country to country'.**

**The A4 sheet did not state that Pentasa did not have a UK marketing authorization for Crohn's disease.**

**The Panel noted that the A4 sheet looked like promotional material. It was in the same style as 'the power of five' booklet considered above. The Pentasa product logo appeared in the bottom right hand corner together with the claims 'Efficacy', 'Compliance', 'Lifestyle', 'Support' and 'Experience'. The Panel considered that, although only provided on request, the A4 sheet was promotional material for Pentasa.**

**The sheet listed those countries in which Pentasa was licensed for active Crohn's disease or for the maintenance of Crohn's disease. The material did not, however, include a clear and prominent statement that it was not so licensed in the UK. A breach of the Code was ruled. With regard to the UK prescribing information, the supplementary information stated that it had to be readily available even though it would not refer to the unlicensed indication. In the Panel's view the UK prescribing information did not have to be on the A4 sheet itself. The UK prescribing information had been available on the stand in 'the power of five' booklet. The Panel ruled no breach in that regard.**

**In relation to the 'power of five' advertisement in the programme, Shire alleged that the adverse event statement was not sufficiently prominent as it was written in the same font as the rest of the paragraph in the bottom left-hand corner of the advertisement.**

**The Panel noted that the adverse event statement was the first statement in a block of text. Although the font size was smaller than other text on the advertisement, given that it was the only block of text on an advertisement with very little other text, the Panel considered that it was sufficiently prominent. No breach was ruled.**

Shire Pharmaceuticals Limited complained about the promotion of Pentasa (mesalazine) by Ferring Pharmaceuticals Ltd. The items at issue were a booklet (ref PEN/011/11/09v2), an A4 sheet (no reference) and an advertisement (no reference). Ferring submitted that all three items were produced by Ferring Global solely for the international Gastro 2009 Congress held in November 2009 in London. The materials were no longer in use. Shire supplied Mezavant XL (mesalazine).

**A 'the power of five' booklet (PEN/011/11/09v2)**

This booklet was obtained from Ferring's stand at the congress.

**1 Page 5 headed '… UC remission rates in active disease'**

Page 5 detailed the results of Marteau *et al* (2005) and featured a bar chart which showed improved remission rates with Pentasa sachets plus Pentasa enema vs Pentasa sachets plus placebo enema.

**COMPLAINT**

Shire was concerned with the claims below the bar chart that illustrated the remission rates of 2g sachets of Pentasa. Ferring had not represented the data accurately from Marteau *et al* by using such claims as 'Nearly 50% improvement in remission rate by adding Pentasa 1g enema' and 'Near normal mean quality of life achieved by 8 weeks and faster using Pentasa sachet + enema combination', referenced to Currie *et al* (2007).

Ferring's response to clarify the 'Nearly 50% improvement …' claim was that as clearly presented on the same page, Marteau *et al* reported that the remission rate at 8 weeks in the group receiving Pentasa 1g enema was 64%, while the remission rate in the group receiving placebo enema was 43%. The improvement in remission rate by adding Pentasa 1g enema was therefore 64 – 43 = 21%/(43/100) = 48.8%. All the necessary figures to support this claim were on the same page.

Shire did not believe that Ferring's method of calculating this measurement was either clear or correct. As the figures were already percentages, multiplying them by 100 gave an erroneous figure. Moreover, the authors stated that the study did not recruit sufficient patients for the assumptions required in the statistical analysis. Shire alleged that the claim was thus unclear and misleading, in breach of Clause 7.2.

Ferring's defence for the claim 'Near normal quality of life …' was that Currie *et al* reported on quality of life (QoL) results from Marteau *et al*. The abstract stated: Rapid improvement in QoL was evident in both treatment arms at 2 weeks (oral mesalazine plus mesalazine enema: Delta = 0.079 [p<0.001]: and oral mesalazine plus placebo enema: Delta = 0.097 [p=0.03]). However, a near normal QoL was achieved more quickly in the oral mesalazine plus mesalazine enema arm, whereby the mean QoL at 4 weeks was 0.921 (sd 0.14), vs 0.859 (sd 0.17) units in the oral mesalazine plus placebo enema arm (p=0.034). At 8 weeks, substantial improvement in QoL was then evidenced in both arms, whereby both had, on average, almost normal QoL compared to the UK standard population (oral mesalazine plus mesalazine enema: mean = 0.922 [Delta from baseline = 0.15; p<0.001] and oral mesalazine plus placebo enema: mean =0.920 [Delta = 0.16: [p<0.001]). The authors concluded: Treatment with mesalazine resulted in improved QoL as measured using a validated and widely used measure (EQ-5D). Near normal mean QoL was achieved by 8 weeks but it was achieved much faster using a combination of oral plus enema mesalazine compared to oral treatment alone. Although both formulations of mesalazine were highly effective, based on patient reported QoL scores the combination treatment was more rapid and consequently should be offered as

first line therapy for patients with mild-to-moderate ulcerative colitis.

Shire stated that the complexity of Ferring's response indicated that the above statement required further clarification which was not evident in the booklet. The data suggested that both groups at 8 weeks had the same QoL parameters, therefore, stating that the Pentasa sachet and enema combination worked faster than the Pentasa sachet plus placebo was misleading.

The mean QoL at 4 weeks for oral mesalazine plus enema was 0.921 (ie assumed nearly normal) and the value for oral mesalazine plus placebo enema was 0.859 (presumed not to be nearly normal). This did not support the claim that combination treatment worked faster. Currie *et al* set 'normal goal' as 1 and a change of 0.03 was determined to be a clinically meaningful change in health status. Shire thus queried how it was possible that 0.921 (at 4 weeks) or even 0.922 at 8 weeks could be described as nearly normal. Both mean scores were at least 0.07 points off normal.

Additionally, Ferring's response also highlighted the results obtained were the authors' conclusion and the findings were not published in a peer-reviewed journal. The data had only been presented as a poster with no substantiation of the validity of the authors' conclusions.

Shire alleged that the lack of supporting evidence and clarification of methodology in obtaining 'near normal quality of life' on this page made the above claims ambiguous and misleading in breach of Clause 7.2.

Shire alleged that the claim '84% of patients were willing to take the sachet + enema combination treatment *in the future*' (emphasis added) was in breach of the spirit of the undertaking that Ferring signed post-arbitration. Ferring had not clarified that 84% of the respondents were willing to take the combination treatment during a relapse of ulcerative colitis and not for long term maintenance therapy. In addition, Marteau *et al* cited to substantiate the claim, asked patients if they would take combination therapy in the case of a relapse. The response was that 84% in the mesalazine enema and 85% in the placebo enema group were willing to take combination therapy in the future. These figures indicated that the placebo enema group were actually more willing to have the combination treatment than the active Pentasa enema group.

The ruling from an independent arbitrator on a similar matter was provided.

During inter-company dialogue Ferring claimed that the page in question related to relapses in active disease and had not alluded to maintenance treatment. Ferring had agreed to amend this claim in future to clarify this still further.

Shire believed that the claim, '84% of patients were willing to take the sachet + enema combination treatment in the future' was open to interpretation, Shire believed that it was misleading and breached Clause 7.2.

## RESPONSE

Ferring disagreed with Shire that claims below the bar chart were unclear and ambiguous.

With regard to the claim 'Nearly 50% improvement in remission rate by adding Pentasa 1g enema', as clearly presented on the same page, Marteau *et al* reported that the remission rate at 8 weeks in the group receiving Pentasa 1g enema was 64%, while the remission rate in the group receiving placebo enema was 43%. The improvement in remission rate by adding Pentasa 1g enema was therefore 64 – 43 = 21%, which was 21/(43/100) = 48.8%. All the necessary figures to support this claim were on the same page.

Ferring would not use this claim without the supporting figures on the same page as this could lead to confusion as to whether this figure was an absolute or relative percentage. In the context of this page, this potential confusion was avoided.

With regard to the claim 'Near normal mean quality of life achieved by 8 weeks and faster using Pentasa sachet + enema', Currie *et al* reported on QoL results from Marteau *et al*. The abstract stated:

> 'Rapid improvement in QoL was evident in both treatment arms at 2 weeks (oral mesalazine plus mesalazine enema: Delta= 0.079 [p<0.001]; and oral mesalazine plus placebo enema: Delta= 0.097 [p=0.03]). However a near normal QoL was achieved more quickly in the oral mesalazine plus mesalazine enema arm, whereby the mean QoL at 4 weeks was 0.921 (sd 0.14), vs 0.859 (sd 0.17) units in the oral mesalazine plus placebo enema arm (p=0.034). At 8 weeks, substantial improvement in QoL was then evident in both arms, whereby both had, on average, almost normal QoL compared to the UK standard population (oral mesalazine plus mesalazine enema: mean = 0.922 [Delta from baseline= 0.15; p<0.001] and oral mesalazine plus placebo enema: mean = 0.920 [Delta = 0.16; [p<0.001]).'

The authors concluded:

> 'Treatment with mesalazine resulted in improved QoL as measured using a validated and widely used measure (EQ-5D). Near normal mean QoL was achieved by 8 weeks but it was achieved much faster using a combination of oral plus enema mesalazine compared to oral treatment alone. Although both formulations of mesalazine were highly effective, based on patient reported QoL scores the combination treatment was more rapid and consequently should be offered as first line therapy for patients with mild-to-moderate UC.'

This was further substantiated by the publication of this study in a peer-reviewed journal, which concluded:

> 'Including 1g mesalazine enemas with 4g oral mesalazine significantly improved HRQoL in patients with active ulcerative colitis.' (Connolly *et al* 2009).

Ferring acknowledged that QoL data were complex but believed that the claim was properly substantiated.

In response to a request from the Authority for further information, Ferring stated that the EQ-5D value found for the UK standard population was 0.86 based on work by Kind *et al* (1999), which was a survey of 3395 men and women aged 18 or over living in the UK.

The EQ-5D results presented in the poster by Currie *et al*, gave mean QoL values at 4 weeks of 0.921 in patients receiving Pentasa sachets plus enemas compared with 0.859 for patients receiving Pentasa sachets alone. By 8 weeks the QoL values had converged so that mean QoL values were 0.922 in patients receiving Pentasa sachets plus enemas compared with 0.920 for patients receiving Pentasa sachets alone. These results compared favourably with the UK population norm of 0.86 and supported the claim that near normal quality of life was achieved by 8 weeks, and faster in patients receiving combination treatment with Pentasa sachets plus enemas.

Ferring did not agree that either claim was in breach of Clause 7.2.

With regard to the claim '84% of patients were willing to take the sachet + enema combination treatment in the future', Shire had alleged a breach of undertaking of an inter-company agreement. Firstly, the undertaking from the earlier arbitration related to an ambiguity in the claim 'Pentasa combination treatment was highly acceptable to patients', and as a result of the arbitration process, Ferring agreed not to use, 'highly acceptable' in this context without appropriate clarification. Ferring did not agree that there had been a breach of this undertaking with Shire.

Marteau *et al* (2005) stated:

> 'Acceptability of combination therapy
> A total of 51/61 patients (84%) in the mesalazine enema and 45/53 patients (85%) in the placebo enema group were willing to take a combination therapy in the future.'

Ferring acknowledged that in this study patients were asked whether they would take combination therapy in the case of relapse. However, Ferring had not made any claim that the acceptability figure related to maintenance therapy and it should be noted that this page clearly related solely to relapses in active disease. Ferring did not agree with Shire that this claim was misleading, or that it was in breach of Clause 7.2.

**PANEL RULING**

The Panel noted that the claim 'Nearly 50% improvement in remission rate by adding Pentasa 1g enema' was below a bar chart which showed a remission rate of 43% in patients treated with oral Pentasa plus placebo enema vs a 64% remission rate for those treated with oral Pentasa plus Pentasa enema. In that regard the Panel considered that it was clear that the claim meant that half as many patients again benefitted from treatment with Pentasa enema compared with those receiving a placebo enema. The Panel did not consider that the claim, in the context in which it appeared, was misleading as alleged. No breach of Clause 7.2 was ruled.

The Panel noted that the claim 'Near normal mean quality of life achieved by 8 weeks and faster using Pentasa sachet + enema combination' was referenced to Currie *et al*. The authors stated that at eight weeks both arms of Marteau *et al* had, on average, almost normal quality of life compared to the UK standard population. The authors did not quantify the normal quality of life in the UK standard population. Quality of life was measured using the EQ-5D measure which had a range of zero (worst possible health state) to 1 (perfect health). The Panel could find no evidence in either Currie *et al* or Connolly *et al* that the 'normal goal' was set as 1 as submitted by Shire. The Panel noted Ferring's submission that the EQ-5D value found for the UK standard population was 0.86.

The Panel noted that Shire's complaint about the claim 'Near normal mean quality of life achieved by 8 weeks and faster using Pentasa sachet + enema combination' was based on its belief that a normal quality of life was an EQ-5D score of 1. In that regard Shire had noted that the Pentasa enema treatment group scored only 0.921 at 4 weeks and 0.922 at 8 weeks. Both scores were more than 0.03 less than 1; a change of 0.03 units in the EQ-5D score was regarded as a clinically meaningful change in health status. Given, however Ferring's submission that the EQ-5D value for the UK standard population was 0.86, the Panel noted that the treatment group had exceeded that at both 4 and 8 weeks. The Panel thus did not consider that the claim was misleading as alleged. No breach of Clause 7.2 was ruled.

During its consideration of this part of the complaint the Panel noted that Currie *et al* reported that at four weeks the mean quality of life in the Pentasa sachet plus Pentasa enema combination arm was 0.921 vs 0.859 units in the Pentasa sachet plus placebo enema arm. In that regard the Panel considered that, compared with the UK standard population (EQ-5D value of 0.86 units), the Pentasa sachet plus placebo enema arm had achieved a near normal quality of life at four weeks and the

Pentasa sachet plus Pentasa enema arm had exceeded it at four weeks. The Panel was thus concerned that the claim 'Near normal mean quality of life achieved by 8 weeks and faster using Pentasa sachet and enema combination' was misleading given the four week data for both treatment groups and Ferring's submission that the normal EQ-5D score of the UK population was 0.86. The Panel requested that Ferring be advised of its views.

**2 Page 7 headed 'Pentasa once daily'**

## COMPLAINT

Shire stated that the sub-heading 'All Pentasa preparations are approved for once daily use' was inaccurate. The prescribing information provided at the back of the booklet stated:

| | |
|---|---|
| Sachets: | Active disease: up to 4g daily in 2-4 divided doses. Maintenance treatment: 2g once daily. |
| Tablets: | Active disease: up to 4g in 2-3 divided doses. Maintenance treatment: 2g once daily. |
| Enema: | Adults – one enema at bedtime. |
| Suppositories: | 1 suppository daily. |

There was a clear discrepancy between the claim and the Pentasa summaries of product characteristics (SPCs). There was no clear distinction between maintenance treatment (to which the claim applied) and active treatment of mild-to moderate ulcerative colitis.

During inter-company dialogue Ferring denied that the claim was inconsistent with Pentasa's SPC as used in the context of the page which included full details of the indications for which each Pentasa presentation could be used with a once daily dose.

The once daily claim and the SPCs for Pentasa sachets and tablets did not match. Shire disagreed that adequate qualification had been provided on this page, as the booklet contained both acute and maintenance data (page 5 was headed '… UC remission rates in active disease') thus readers would assume that the claim related to active disease and maintenance treatment. Hence Shire asserted that the manner in which this claim was currently portrayed was misleading and ambiguous in breach of Clause 7.2.

## RESPONSE

Ferring stated that the sub-heading 'All Pentasa presentations are approved for once daily use' was not inaccurate, nor was it inconsistent with the Pentasa SPCs as used in the context of the page, which included full details of the indications for which each Pentasa presentation could be used with a once daily dose. It was true that Pentasa tablets and sachets had a once daily dose approved only for maintenance treatment, and this was clearly itemised below this claim. However, Pentasa suppositories and enema were approved for once daily dosing for both active disease and maintenance treatment. Ferring confirmed that this claim would not be used unless it was adequately clarified. As adequate clarification had been prominently provided on this page in the form of a comprehensive listing for each Pentasa formulation, Ferring did not agree with Shire's assertion that this page was in breach of Clause 7.2.

## PANEL RULING

The Panel noted that the page was headed 'Pentasa once daily' and sub-headed 'All Pentasa presentations are approved for once daily use'. These claims were qualified in the bullet points below and in that regard Ferring, in its letter to Shire dated 18 December, stated that adequate clarification had been given such that there was no breach of the Code. The Panel noted, however, that it was a principle of the Code that claims in promotional material must be capable of standing alone as regards accuracy etc. In general claims should not be qualified by the use of footnotes and the like as referred to in the supplementary information to Clause 7, General.

The Panel considered that the claims 'All Pentasa presentations are approved for once daily use' beneath the heading 'Pentasa once daily' were misleading as alleged. A breach of Clause 7.2 was ruled.

**B A4 sheet – Worldwide markets where Pentasa is available for the treatment of Crohn's disease (no reference)**

## COMPLAINT

Shire noted that the A4 sheet listed the countries where Pentasa was licensed for both active and maintenance treatment of Crohn's disease. The UK SPC for Pentasa did not include the Crohn's disease indication.

The sheet lacked the required prescribing information as it contained an off-licence use/indication of Pentasa and both the brand name and a non-proprietary name of the medicine.

Ferring had responded stating that the sheet was available at its exhibition stand and, as required by the supplementary information to Clause 3, as it referred to unlicensed indications it could not be considered to be a promotional item and could not include UK prescribing information.

Shire noted that the supplementary information to Clause 3 included:

- '… in relation to an unlicensed indication, UK approved prescribing information must be readily available for a medicine authorized in the UK even though it will not refer to the unlicensed

indication …'
- 'promotional material for a medicine or indication that does not have a UK marketing authorization must be clearly and prominently labelled to that effect'
- '… it must be stated that registration conditions differ from country to country'.

The A4 sheet did not have prescribing information that was readily available, nor state that Pentasa did not have a UK marketing authorization for Crohn's disease.

Shire alleged a breach of Clause 3.

## RESPONSE

Ferring confirmed that the sheet was available only on request at the stand as described in the supplementary information to Clause 3. As the sheet only listed countries where Pentasa was licensed for the treatment of Crohn's Disease it was not considered to be a promotional item for the UK and therefore did not include UK prescribing information. As a non-promotional piece, this item was not formally signed off in the UK, although Ferring UK staff provided guidance on its content. Ferring submitted that UK prescribing information was freely available on the stand. Ferring did not agree with Shire's assertion that the provision of this sheet on request was in breach of Clauses 3.2 or 4.1.

In response to a request for further information, Ferring submitted that although there was no promotional literature or exhibition panels that included information about the use of Pentasa in Crohn's disease, a significant proportion of delegates from Europe attended the meeting. Ferring believed it was appropriate to have a list of countries in which the indication for acute or maintenance treatment in Crohn's disease was approved to assist in discussions with these delegates should they wish to discuss these indications. As these discussions could take place at the exhibition stand, which would be a promotional setting in the UK, Ferring considered it appropriate to provide a sheet consistent with the supplementary information to Clause 3, which advised that the names of countries with authorizations for indications that were unlicensed in the UK should be available. This sheet was not visible on the stand and was available only on request.

## PANEL RULING

The Panel noted that the A4 sheet had the appearance of promotional material. It was in the same style as 'the power of five' booklet considered above. The Pentasa product logo appeared in the bottom right hand corner together with the claims 'Efficacy', 'Compliance', 'Lifestyle', 'Support' and 'Experience'. The Panel considered that, although only provided on request, the A4 sheet was promotional material for Pentasa.

The sheet listed those countries in which Pentasa was licensed for active Crohn's disease or for the maintenance of Crohn's disease. The material did not, however, include a clear and prominent statement that it was not so licensed in the UK. A breach of Clause 3.2 was ruled. With regard to the UK prescribing information, the supplementary information stated that it had to be readily available even though it would not refer to the unlicensed indication. In the Panel's view the UK prescribing information did not have to be on the A4 sheet itself. The UK prescribing information had been available on the stand in 'the power of five' booklet. The Panel ruled no breach of Clause 3.2 in that regard.

The Panel noted that Ferring had referred to Clause 4.1. Whilst Shire had referred to the absence of prescribing information it did so in relation to the supplementary information to Clause 3 and did not cite Clause 4.1. There was no allegation of a breach of Clause 4.1 and so the Panel made no ruling in that regard.

### C 'the power of five' advertisement in the Gastro 2009 programme (no reference)

## COMPLAINT

Shire alleged that the adverse event statement was not sufficiently prominent as it was written in the same font as the rest of the paragraph in the bottom left-hand corner of the advertisement.

Shire alleged a breach of Clause 4.10.

## RESPONSE

Ferring acknowledged that this item was in breach of Clause 5.6 as incomplete wording was used in this abbreviated advertisement, the statement omitted the final sentence, 'Adverse events should also be reported to Ferring Pharmaceuticals Ltd'.

## PANEL RULING

The Panel noted that the adverse event statement was the first statement in a block of text. Although the font size was smaller than other text on the advertisement, given that it was the only block of text on an advertisement with very little other text, the Panel considered that it was sufficiently prominent. No breach of Clause 4.10 was ruled.

**Complaint received** **23 February 2010**

**Case completed** **25 May 2010**