CASE AUTH/3039/5/18

TILLOTTS v DR FALK

Promotion of Budenofalk

Tillotts Pharma UK Limited complained about a Budenofalk (budesonide) advertisement used by Dr Falk Pharma UK Ltd. Budenofalk was available as 3mg gastro-resistant capsules, 9mg gastro-resistant granules and a 2mg/dose foam enema.

Budenofalk capsules was indicated for the induction of remission of mild to moderate active Crohn's disease in patients with mild to moderate active Crohn's disease affecting the ileum and/or the ascending colon, the induction of remission of active collagenous colitis and for the treatment of autoimmune hepatitis whilst Budenofalk granules was indicated for the induction of remission of mild to moderate active Crohn's disease in patients with mild to moderate active Crohn's disease affecting the ileum and/or the ascending colon and the induction of remission of active collagenous colitis. Budenofalk foam was only indicated for the treatment of active ulcerative colitis that was limited to the rectum and the sigmoid colon.

Tillotts was concerned that the pharmaceutical form was not clearly stated on the advertisement given that Budenofalk was the root name for three separate products. The advertisement was headed by three indications: autoimmune hepatitis, Crohn's disease and collagenous colitis however only Budenofalk 3mg capsules was licensed for all three indications. Tillotts alleged that the advertisement was thus misleading. The ambiguity surrounding which product was being advertised might also represent a further breach, as the specific marketing authorisation being advertised was not clear. The advertisement implied that all forms of Budenofalk were indicated for all three conditions.

Tillotts further noted the ambiguity in the first of three bullet points which stated 'The only budesonide with three indications'. Given that the specific preparation was not clearly identified, the claim was inaccurate as neither the granule nor the foam formulation had three indications (they had two and one indication, respectively). In addition, the claim should specify that it referred to an orally administered budesonide, as certain inhaled budesonides offer three indications, such as Rhinocort Aqua nasal spray.

Tillotts noted that the prescribing information referred to Budenofalk granules and capsules and stated in the indication section that autoimmune hepatitis related to the capsules only. The prescribing information was the only place on the page where the product names were mentioned and Tillotts alleged that this needed to be stated more prominently in the body of the advertisement. The reader should not be relied upon to read the prescribing information to understand the subject of the advertisement.

The detailed response from Dr Falk appears below.

The Panel noted that the top half of the advertisement bore photographs of 3 separate woman and the claim 'Getting on with their lives By getting on with their steroid'. Above each woman was a description of her condition: autoimmune hepatitis, Crohn's disease and collagenous colitis respectively. A bold red strip beneath the photographs read, on the right, 'Budenofalk' above in smaller font 'Budesonide, the Dr Falk way'. To the left appeared three bullet point claims, the first of which read 'The only budesonide with three indications'. The prescribing information appeared beneath.

The Panel noted the prominent reference to 'Budenofalk' and that there were three relevant products which had Budenofalk as the root name. Only one product, Budenofalk 3mg capsules was indicated for all three conditions. In the Panel's view the failure to clearly identify the product in the body of the advertisement either implied that all three Budenofalk products were each licensed for all three conditions and that was not so, or was otherwise unclear which Budenofalk product was so licensed. The advertisement was misleading in this regard. The Panel also considered that Dr Falk had failed to maintain high standards. Breaches of the Code were ruled.

In the Panel's view the claim 'the only budesonide with three indications' in isolation was inaccurate, however, the context in which it appeared was relevant. The Panel noted that the claim in question appeared in relatively small font on the left-hand side of a red box, to the right of which appeared the prominent brand name Budenofalk followed by Budesonide, the Dr Falk way beneath. In the Panel's view, the relevant qualification, namely that the budesonide product in question was a Budenofalk product, appeared prominently and within the immediate visual field of the claim in question. In addition, it was clear that the three indications referred to were autoimmune hepatitis, Crohn's disease and collagenous colitis as stated at the top of the advertisement. On balance, the Panel considered that the claim in question 'The only budesonide with three indications' was sufficiently qualified such that, within the context of the advertisement, it was not misleading as alleged and thus ruled no breaches of the Code.

Tillotts Pharma UK Limited complained about a Budenofalk (budesonide) advertisement (ref DrF17/159) used by Dr Falk Pharma UK Ltd. Budenofalk was available as 3mg gastro-resistant capsules, 9mg gastro-resistant granules and a 2mg/dose foam enema.

Budenofalk capsules was indicated for the induction of remission of mild to moderate active Crohn's disease in patients with mild to moderate active Crohn's disease affecting the ileum and/or the ascending colon, the induction of remission of active collagenous colitis and for the treatment of autoimmune hepatitis whilst Budenofalk granules was indicated for the induction of remission of mild to moderate active Crohn's disease in patients with mild to moderate active Crohn's disease affecting the ileum and/or the ascending colon and the induction of remission of active collagenous colitis. Budenofalk foam was only indicated for the treatment of active ulcerative colitis that was limited to the rectum and the sigmoid colon.

COMPLAINT

Tillotts was concerned that the pharmaceutical form was not clearly stated on the advertisement given that Budenofalk was the root name for three separate products ie Budenofalk 3mg capsules, Budenofalk 9mg granules and Budenofalk foam enema all of which contained budesonide. The advertisement was headed by three indications: autoimmune hepatitis, Crohn's disease and collagenous colitis however only Budenofalk 3mg capsules were licensed for all three indications. Tillotts alleged that the advertisement was thus misleading, and in

breach of the Code. The ambiguity surrounding which product was being advertised might also represent a further breach, as the specific marketing authorisation being advertised was not clear. The advertisement implied that all forms of Budenofalk were indicated for all three conditions.

Tillotts further noted the ambiguity in the first of three bullet points which stated 'The only budesonide with three indications'. Given that the specific preparation was not clearly identified, the claim was inaccurate as neither the granule nor the foam formulation had three indications (they had two and one indication, respectively). In addition, the claim should specify that it referred to an orally administered budesonide, as certain inhaled budesonides offer three indications, such as Rhinocort Aqua nasal spray.

Tillotts noted that the prescribing information referred to Budenofalk granules and capsules and stated in the indication section that autoimmune hepatitis indicated related to the capsules only. The prescribing information was the only place on the page where the product names were mentioned and Tillotts considered that this needed to be stated more prominently in the body of the advertisement. The reader should not be relied upon to read the prescribing information to understand the subject of the advertisement.

Tillotts alleged that the advertisement was misleading, in breach of Clause 7.2. The matter also appeared to be a failure to uphold high standards by Dr Falk and in breach of Clause 9.1.

RESPONSE

Dr Falk submitted that the complaint was not succinct and did not allege more than one breach of the Code. The complaint appeared to be concerned with the fact that there were three licensed indications stated at the top of the advertisement along with the statement 'The only budesonide with three indications', without listing specific formulations within the Budenofalk range.

Budenofalk 3mg capsules were licensed for the three indications listed. The statement 'The only budesonide with three indications' was a fact. It was also a fact that this budesonide was in the Budenofalk range. Budenofalk, budesonide, was clearly stated in the advertisement. The advertisement was very brief and there was no suggestion in it that other formulations might or might not have these indications as the prescribing information clearly showed the indications and it was a general expectation and practice that readers consulted the prescribing information and/or the summary of product characteristics (SPC) and/or referenced works such as the British National Formulary (BNF) and MIMS. Indeed, the Code itself expected the reader to 'form their own opinion of the therapeutic value of the medicine'.

Dr Falk noted that the complainant also suggested inaccuracy because a product in a different therapeutic area, Rhinocort Aqua nasal spray, was indicated for seasonal and perennial allergic rhinitis, vasomotor rhinitis and nasal polyps. Dr Falk thus agreed that there was a budesonide product in a different therapeutic area with three indications but did not consider that it was relevant because health professionals dealing with autoimmune hepatitis, Crohn's disease and collagenous colitis, diseases of the lower gastrointestinal tract, were not likely to confuse Budenofalk with a treatment for nasal conditions, even in the unlikely event that they worked in both therapeutic areas. In addition, the advertisement was only placed in specialist publications targeted at gastroenterologists, such as Frontline Gastroenterology, Colorectal Disease, Journal of Crohn's and Colitis and IBD News.

Dr Falk did not consider that any health professional would be misled by the advertisement in question nor find it ambiguous. Dr Falk stated that in its view, the complainant had not proven that the advertisement breached Clause 7.2.

Finally, Dr Falk noted that the complainant had not explained how the advertisement failed to uphold high standards. Dr Falk maintained that the advertisement met the high standards required, particularly when considered in the light of the supplementary information to Clause 9.1.

PANEL RULING

The Panel noted that the top half of the advertisement bore photographs of 3 separate woman and the claim 'Getting on with their lives By getting on with their steroid'. Above each woman appeared a description of her condition: autoimmune hepatitis, Crohn's disease and collagenous colitis respectively. A bold red strip beneath the photographs read, on the right, 'Budenofalk' above in smaller font 'Budesonide, the Dr Falk way'. To the left appeared three bullet point claims, the first of which read 'The only budesonide with three indications'. The prescribing information appeared beneath.

The Panel noted Tillotts' submission that Budenofalk was the root name given to three separate products. The Panel noted that according to their respective SPCs Budenofalk 9mg granules were indicated for induction of remission in mild to moderate active Crohn's disease of the ileum and/or ascending colon and induction of remission in patients with active collagenous colitis; Budenofalk 2mg rectal foam for the treatment of active rectum and colon ulcerative colitis; and Budenofalk 3mg capsules for induction of remission in patients with mild to moderate active Crohn's disease of the ileum and ascending colon, induction of remission in patients with active collagenous colitis and for autoimmune hepatitis.

The Panel noted the prominent reference to 'Budenofalk' and that there were three relevant products which had Budenofalk as the root name. Only one product, Budenofalk 3mg capsules was indicated for all three conditions. In the Panel's view the failure to clearly identify the product in the body of the advertisement either implied that all three Budenofalk products were each licensed for all three conditions and that was not so, or was otherwise unclear which Budenofalk product was so licensed. The advertisement was misleading in this regard. In the Panel's view, that the prescribing information made it clear that only the capsules were indicated for autoimmune hepatitis did not alter the otherwise misleading implication of the advertisement. The main body of the advertisement had to be capable of standing alone with regard to the requirements of the Code and, on this point, could not be qualified by the use of footnotes or by reference to the content of prescribing information. In addition, the Panel noted that the prescribing information referred to Budenofalk granules under presentation and only referred to the capsule formulation in brackets beside the autoimmune hepatitis indication. A breach of Clause 7.2 was ruled. The Panel considered that Dr Falk had failed to maintain high standards and a breach of Clause 9.1 was ruled.

The Panel noted Dr Falk's submission that although there was a budesonide product in a different therapeutic area with three rhinitis indications, it was not relevant because health professionals dealing with diseases of the lower gastrointestinal tract were not likely to confuse Budenofalk with a treatment for nasal conditions. The Panel noted that Tillott's allegation was not about health professionals confusing Budenofalk with the treatment of nasal conditions; Tillotts alleged that by not referring to orally administered budesonide, the claim 'the only budesonide with three indications' was inaccurate as certain inhaled budesonides such as

Rhinocort Aqua nasal spray offered three indications. In the Panel's view the claim 'the only budesonide with three indications' in isolation was inaccurate, however, the context in which it appeared was relevant. The Panel noted that the claim in question appeared in relatively small font on the left-hand side of a red box, to the right of which appeared the prominent brand name Budenofalk followed by Budesonide, the Dr Falk way beneath. In the Panel's view, the relevant qualification, namely that the budesonide product in question was a Budenofalk product, appeared prominently and within the immediate visual field of the claim in question. In addition, it was clear that the three indications referred to were autoimmune hepatitis, Crohn's disease and collagenous colitis as stated at the top of the advertisement. On balance, the Panel considered that the claim in question 'The only budesonide with three indications' was sufficiently qualified such that, within the context of the advertisement, it was not misleading as alleged and thus ruled no breach of Clause 7.2 and subsequently no breach of Clause 9.1 was ruled.

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During its consideration of this case the Panel noted that Budenofalk 3mg capsules and 9mg granules were both indicated for the induction of remission of mild to moderate active Crohn's disease in patients with mild to moderate active Crohn's disease affecting the ileum and/or the ascending colon and Budenofalk foam was indicated for the treatment of active ulcerative colitis that was limited to the rectum and the sigmoid colon. The Panel noted that the advertisement simply listed Crohn's disease as one of the indications of Budenofalk thereby implying that they were indicated for all presentations of Crohn's disease and that was not so. The Panel queried whether this was in line with the requirements of Clause 3.2 which stated that the promotion of a medicine must be in accordance with the terms of its marketing authorization and must not be inconsistent with the particulars listed in its summary of product characteristics.

The Panel also noted its comments above about the content of the prescribing information and considered it would be advisable for Dr Falk to review its prescribing information to ensure that it was accurate and complied with the Code.

The Panel requested that Dr Falk be advised of its concerns.

Complaint received **11 May 2018**

Case completed **13 July 2018**