CASE AUTH/3713/11/22

TILLOTTS PHARMA v DR FALK PHARMA

Budenofalk 3mg capsules digital advertisement

CASE SUMMARY

This case was in relation to the failure to withdraw and continued use of a digital advertisement for Budenofalk 3mg capsules, 12 weeks after agreeing during inter-company dialogue that it would be withdrawn.

The Panel noted Dr Falk's submission that the withdrawn digital advertisement had been brought back into use by a third party agency, in error, without Dr Falk's knowledge.

The Panel ruled a breach of the following Clause of the 2021 Code because it considered that Dr Falk had inadequate control of the material and its failure to adequately withdraw the digital advertisement meant that high standards had not been maintained:

Breach of Clause 5.1	**Failing to maintain high standards**

This summary is not intended to be read in isolation.
For full details, please see the full case report below.

FULL CASE REPORT

A complaint was received from Tillotts Pharma UK Ltd about Dr Falk Pharma UK Ltd.

COMPLAINT

Tillotts stated that it contacted Dr Falk requesting withdrawal of a digital advertisement based on an alleged unsubstantiated and misleading claim. Intercompany dialogue concluded in August 2022 with Dr Falk stating the advertisement in question was currently in review and updated to remove the text in question. Tillotts alleged that the advertisement was still in use 12 weeks later. Tillotts stated that its complaint was in relation to failure to withdraw and continued use (Clause 5.1) and that no complaint was being made at this time regarding the advertisement.

Budenofalk 3mg capsules digital advertisement UI 2200023 ('the advertisement') was the subject of inter-company dialogue between Tillotts Pharma UK Ltd ('Tillotts') and Dr Falk Pharma UK Ltd ('Dr Falk').

The advertisement stated 'Recommended by the BSG for its low-risk status'. Tillotts stated that the guidance used to substantiate this claim (Kennedy NA, *et al.* 2020) was specific to the management of inflammatory bowel disease during the COVID-19 pandemic, and listed several

'therapy specific considerations' regarding IBD [inflammatory bowel disease] medications which included the following in respect of corticosteroids:

'► Corticosteroids
  - Should be avoided if possible but will still be necessary for some who should then observe 'shielding' while prednisolone dose is ≥20 mg daily.
  - High dose steroids are an established risk factor for respiratory tract infection and opportunistic infection in IBD and septicaemia.
  - Rapid tapering (10 mg/week) should be considered where possible. This must be balanced against the risks of extending steroid exposure overall by decreasing dose too quickly.
  - Consider budesonide (Entocort, Budenofalk, 9 mg/day 8 weeks) for active small bowel and ileo-caecal CD.'

Tillotts stated that there was no recommendation to use Budenofalk, or oral budesonide, as claimed in the advertisement.

Tillotts stated that the BSG guidance did categorise budesonide as posing the lowest risk of serious COVID-19 disease for patients with inflammatory bowel disease but to state 'low risk status' without providing this context implied that Budenofalk is low risk whenever prescribed within its indication for liver and GI [gastrointestinal] diseases, which was not the case as evidenced by the contraindications, special warnings, and precautions for use in sections 4.3 and 4.4 respectively of the Budenofalk 3mg capsules summary of product characteristics.

Tillotts stated the claim 'Recommended by the BSG for its low-risk status' was inaccurate and misleading by distorting the referenced guidance provided by the BSG (Clause 6.1) and was not substantiated by any of the six references provided (Clause 6.2). The claim exaggerated the safety of Budenofalk and did not therefore encourage the rational use of the medicine (Clause 14.4). Collectively, Tillotts stated that these breaches represented a failure to maintain high standards (Clause 5.1).

Tillotts stated that it initiated inter-company dialogue on 19 August 2022, requesting withdrawal of the advertisement as detailed above. In response, Dr Falk confirmed in a letter dated 26 August 2022 that 'the material referenced above is currently in review and updated to remove the text in question'.

It had come to Tillotts' attention that, at the time of writing to the PMCPA, the advertisement was still in use. Tillotts alleged there had either been a failure of Dr Falk's withdrawal process, or a change in Dr Falk's commitment to withdraw the material.

Although neither the Code nor the letter from Dr Falk dated 26 August 2022 set a timeline for withdrawal of material, it was Tillotts' belief that to allow a period of 12 weeks to pass was unacceptable. Tillotts alleged that failure to withdraw the advertisement and its continued use collectively demonstrated a failure to maintain high standards and was, in the opinion of Tillotts, in breach of Clause 5.1 of the Code.

Tillotts stated that Dr Falk had been informed of its intention to raise this matter as a complaint with the PMCPA. Tillotts therefore requested that the PMCPA accepted this as a formal complaint as set out in Paragraph 5.3 of the PMCPA Constitution and Procedure for a potential breach of Clause 5.1 of the Code.

RESPONSE

Dr Falk submitted that Tillotts first contacted it on Friday 19 August 2022 to request withdrawal of material UI 2200023. As stated in its subsequent response to Tillotts, the advertisement was already in review. UI 2200023 related to the management of IBD patients during the COVID-19 pandemic. The review had decided that the material was no longer critical for management of IBD patients and replacement materials with a different focus were in preparation. In the light of that, it was agreed to withdraw the material as requested by Tillotts.

Dr Falk submitted that the following actions were taken:

- It contacted the agency handling distribution of Dr Falk's advertisements to instruct that both digital and printed advertisements be withdrawn. This was initially verbally, followed up by email on 24 August. The agency confirmed on the same day that the required actions were being taken. However, it was noted that it was too late to withdraw every instance, but that full withdrawal would be completed by the end of the month.
- It responded to Tillotts on 26 August 2022 to confirm that the piece would be withdrawn.

On receiving a further letter from Tillotts on 16 November, Dr Falk discovered that the digital (not print) material had been reintroduced by the agency. Dr Falk was not previously aware of this. Dr Falk contacted the agency and again instructed removal and investigation into what had occurred. It was shown to be entirely an error and not a deliberate reintroduction of the material by either party. However, Dr Falk recognised that under Clause 1.24 it was responsible for the actions of third parties.

Dr Falk submitted that prior to this complaint concerning withdrawal of UI 22000223, Tillotts originally complained about UI 2200023 because of the statement '*Recommended by the BSG for its low risk status.*' Reference was made to the paper '*British Society of Gastroenterology guidance for management of inflammatory bowel disease during the COVID-19 pandemic*' by Kennedy N A *et al*. In Table 1 of the paper, patients taking budesonide were classified as being at lowest risk of severe COVID-19 and in the section 'Therapy Specific Considerations', it was stated, '*Consider budesonide (Entocort, Budenofalk, 9mg/day 8 weeks) for active small bowel and ileo-caecal CD*'. Dr Falk submitted that the statement in UI 2200023 clearly and directly related to Kennedy for substantiation, accurately reflected the status of budesonide as described by the paper and therefore could not be misleading or exaggerated. Dr Falk submitted that it did not impact negatively on patient safety. Dr Falk withdrew the material because the need for focus on the impact of medication on COVID-19 had passed.

PANEL RULING

The Panel noted Tillotts' allegation that Dr Falk's failure to withdraw and continued use of a Budenofalk digital advertisement (UI 2200023), 12 weeks after agreeing during inter-company dialogue that it would be withdrawn, demonstrated a failure to maintain high standards.

The Panel noted that the outcome of inter-company dialogue was a matter for companies. The fact that a company might have not honoured its inter-company commitments was not in itself necessarily a breach of the Code. Such a commitment was not the same as a formal

undertaking given to the PMCPA by a company ruled in breach of the Code. The Panel noted, however, that it was important that companies complied with such inter-company commitments and failing to implement an inter-company agreement might indicate that previous inter-company dialogue had ultimately been unsuccessful.

The Panel noted Dr Falk's submission that the withdrawn digital advertisement had been brought back into use by a third party agency, in error, without Dr Falk's knowledge.

Clause 1.24 states that companies are responsible under the Code for the acts and omissions of their third parties which come within the scope of the Code, even if they act contrary to the instructions which they have been given; the Panel noted Dr Falk's acknowledgement that it was, therefore, responsible for the error made by its third party in this regard.

The Panel considered that a company's withdrawal process was fundamental to it having adequate control of its active materials and, therefore, it was important that employees and third parties complied promptly and fully to withdrawal instructions. While it appeared that Dr Falk had been let down by its third party in this regard, it was nonetheless responsible for the reintroduction of the material.

The Panel considered that Dr Falk had inadequate control of the material and its failure to adequately withdraw the digital advertisement meant that high standards had not been maintained; a **breach of Clause 5.1** was ruled.

While the Panel had concerns about the claim 'Recommended by the BSG for its low-risk status', it noted that Tillotts' complaint was in relation to the failure to withdraw the digital advertisement and that Tillotts had stated that its complaint did not concern the content of the advertisement at this time; therefore, the Panel made no ruling in this regard.

Complaint received **17 November 2022**

Case completed **24 January 2024**