CASE AUTH/3143/1/19

TILLOTTS v FERRING

Failure to withdraw material

Tillotts Pharma UK complained that Ferring Pharmaceuticals Ltd had failed to honour an inter-company agreement to withdraw a Cortiment (budesonide prolonged release tablets) leavepiece. Cortiment was indicated in adults for the induction of remission in patients with mild to moderate active ulcerative colitis where 5 ASA treatment was not sufficient. The leavepiece was entitled 'Guidance on Prescribing Cortiment by brand' and included the claim relating to Cortiment that 'Generic budesonides lack this unique [multimatrix] MMX structure'.

Tillotts initiated inter-company dialogue with Ferring and objected, *inter alia*, to the use of the term 'generic budesonides' in the leavepiece at issue. As there were no generic oral budesonides available in the UK, the term was inaccurate and misleading and Tillotts asked that the material be withdrawn.

Tillotts was thus concerned to note that three weeks later the leavepiece in question was distributed from the Ferring stand at the Scottish Society of Gastroenterology (SSG) meeting in November 2018. This clearly meant that the term 'generic' had not been revised in future promotional activity as Ferring stated it would be.

Tillotts wrote to Ferring on 17 December to ask why the material had been used at the SSG meeting. There had either been a failure of Ferring's withdrawal process, or a change in Ferring's commitment to withdraw the material. In its response of 20 December, Ferring confirmed that the leavepiece had been withdrawn as of 18 December and replaced with a new piece.

Tillotts noted that although neither the Code nor the letter from Ferring of 25 October set a timeline for withdrawal of material, to allow nearly 8 weeks to pass was unacceptable and demonstrated a failure to maintain high standards. Tillotts also alleged that use of the material at one promotional event, and possibly others, during this eight week period was also a failure to maintain high standards.

The detailed response from Ferring is given below.

The Panel noted that although undertakings given during the course of inter-company dialogue were not covered by the Code and were thus not subject to the requirements of the Code, it was important that companies complied with such undertakings. Failing to implement an inter-company undertaking might indicate that previous inter-company dialogue had ultimately been unsuccessful.

The Panel noted that Ferring had informed Tillotts that it agreed to withdraw the material. The Panel considered, in the circumstances, it was not unreasonable for Tillotts to assume that the leavepiece had been withdrawn. This had not happened until some weeks later. The Panel might be sympathetic to the submission that Ferring was waiting for comment from Tillotts regarding another matter it had raised before changing the leavepiece if Ferring had made this clear to Tillotts. The Panel disagreed with Ferring's submission about the use of the claim 'generic budesonides lack this … structure'. In the Panel's view, the claim was misleading as oral budesonide was not available as a generic in the UK. The term 'generic' had a particular meaning in relation to medicines. The Panel considered, therefore, that high standards had not been maintained and a breach of the 2016 Code was ruled. The Panel considered that this ruling covered both the failure to withdraw the leavepiece and its continued use.

Tillotts Pharma UK Limited complained that Ferring Pharmaceuticals Ltd had failed to honour an inter-company agreement to withdraw a Cortiment (budesonide prolonged release tablets) leavepiece (ref COR/2078/2017/UK). Cortiment was indicated in adults for the induction of remission in patients with mild to moderate active ulcerative colitis where 5 ASA treatment was not sufficient. The leavepiece was entitled 'Guidance on Prescribing Cortiment by brand' and included the claim relating to Cortiment that 'Generic budesonides lack this unique [multimatrix] MMX structure'.

COMPLAINT

Tillotts explained that on 16 October 2018 it initiated inter-company dialogue with Ferring and objected, *inter alia*, to the use of the term 'generic budesonides' in the leavepiece at issue. As there were no generic oral budesonides available in the UK, the term was inaccurate and misleading and Tillotts asked that the material be withdrawn. The letter named the four brands available in the UK.

The response from Ferring dated 25 October included:

> 'We acknowledge your statement in relation to the use of the term 'generic' and shall revise this in future promotional activity.
>
> We confirm withdrawal of the leave piece in question and replacement of the term generic with another term.'

Tillotts was thus concerned to note that three weeks later the leavepiece in question was distributed from the Ferring stand at the Scottish Society of Gastroenterology (SSG) meeting held 14-16 November. This clearly meant that the term 'generic'

had not been revised in future promotional activity as Ferring stated it would be.

Tillotts wrote to Ferring on 17 December to ask why the material had been used at the SSG meeting. There had either been a failure of Ferring's withdrawal process, or a change in Ferring's commitment to withdraw the material. In its response of 20 December, Ferring confirmed that the leavepiece had been withdrawn as of 18 December and replaced with a new piece with the specified changes. Ferring did not, however, explain why the leavepiece had been used at the SSG meeting as requested.

Tillotts noted that although neither the Code nor the letter from Ferring of 25 October set a timeline for withdrawal of material, to allow nearly 8 weeks to pass was unacceptable and demonstrated a failure to maintain high standards in breach of Clause 9.1. Tillotts also alleged that use of the material at one promotional event, and possibly others, during this eight week period was also in breach of Clause 9.1, as Ferring had stated that use of the term 'generic' with regard to budesonide products would be revised in future promotional activity.

RESPONSE

Ferring denied breaches of Clause 9.1. The company submitted that in the spirit of goodwill, it offered to amend the material in relation to the word 'generic' although it did not accept that its use was inappropriate. Ferring noted that Tillotts did not acknowledge receipt of Ferring's response or acknowledge its counter arguments and as no timeframe had been stated in Ferring's letter of 25 October, Ferring allowed for sufficient time to elapse before taking action. The obvious consideration was that Tillotts might require further action in relation to a second point which had also been discussed. Ferring would not want to change the material twice in a short space of time if Tillotts raised further points (which could often be the case in inter-company exchanges).

Ferring stated that in a genuine grammatical error, its letter of 25 October implied that the material had been withdrawn. The letter referred to revising future promotional activity and stated:

> 'We confirm withdrawal of the leave piece in question and replacement of the term generic with another term.'

but should have stated:

> 'We confirm our willingness to withdraw the leave piece in question and replacement of the term generic with another term.'

Ferring apologised for the confusion caused.

In the absence of a response from Tillotts, Ferring stated that it continued with business as usual, including the dissemination of material for use at the SSG meeting. Ferring noted that it responded to Tillotts on 25 October; material was sent to the SSG meeting 2 weeks later so that it could be used at the meeting (14-16 November). Ferring noted that at that point, it had not received any response from Tillotts.

Ferring submitted that it waited 7 weeks for a response from Tillotts and it took the unilateral decision on 18 December to withdraw the leavepiece in question. The withdrawal notice (copy provided) was issued by Ferring before the receipt of the letter from Tillotts (dated 17 December, received 20 December). Ferring submitted that its withdrawal email clearly denoted the procedure that needed to be followed and aligned with its standard operating procedure (SOP) on the management of promotional materials (copy provided).

Ferring responded to Tillotts on 20 December to acknowledge receipt of the letter and confirmed when the leavepiece in question was actually withdrawn. Ferring noted that it never provided a timeframe for withdrawal of the material in question. The difference of opinion in relation to the term 'generic' was not a patient safety issue. Ferring did not consider that in the circumstances, the timelines involved in the withdrawal were inappropriate and the company denied a breach of Clause 9.1. Ferring further denied the alleged breach of Clause 9.1 in relation to the continued use of the leavepiece.

PANEL RULING

The Panel noted that although undertakings given by companies during the course of inter-company dialogue were not covered by the Code and were thus not subject to the requirements of the Code, it was important that companies complied with such undertakings. Failing to implement an inter-company undertaking might indicate that previous inter-company dialogue had ultimately been unsuccessful.

The Panel noted that Ferring had informed Tillotts that it agreed to withdraw the material. The Panel considered, in the circumstances, it was not unreasonable for Tillotts to assume that the leavepiece had been withdrawn. This had not happened until some weeks later. The Panel might be sympathetic to the submission that Ferring was waiting for comment from Tillotts regarding another matter it had raised before changing the leavepiece if Ferring had made this clear to Tillotts. The Panel disagreed with Ferring's submission about the use of the claim 'generic budesonides lack this … structure'. In the Panel's view, the claim was misleading as oral budesonide was not available as a generic in the UK. The term 'generic' had a particular meaning in relation to medicines. The Panel considered, therefore, that high standards had not been maintained and a breach of Clause 9.1 was ruled. The Panel considered that this ruling covered both the failure to withdraw the leavepiece and its continued use.

Complaint received **7 January 2019**

Case completed **19 March 2019**