CASE AUTH/3716/11/22

TILLOTTS PHARMA v FERRING PHARMACEUTICALS

Pentasa leavepiece

CASE SUMMARY

This case was in relation to the failure to withdraw and continued use of a Pentasa leavepiece containing incorrect prescribing information, 11 weeks after confirming during inter-company dialogue that it had been withdrawn.

The Panel noted Ferring's acknowledgement that it had failed to fully withdraw all hyperlinks to the leavepiece at issue.

The Panel ruled a breach of the following Clause of the 2021 Code because it considered that Ferring had inadequate control of the material and its failure to fully withdraw the leavepiece 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 ('Tillotts') about Ferring Pharmaceuticals Ltd ('Ferring').

COMPLAINT

Tillotts stated that, following inter-company dialogue between Tillotts and Ferring, Ferring agreed to withdraw all materials using prescribing information erroneously stating that Pentasa tablets could be 'administered once daily or in two to four divided doses'. Tillotts contacted Ferring on 5 September 2022 to inform it that material using this version of prescribing information was still available on a Ferring website. This material had not been removed and was still in use. Tillotts' complaint was in relation to the failure to withdraw and the continued use of this material (Clause 5.1). Tillotts stated that no complaint was being made at this time regarding the leavepiece.

A Pentasa adult summary leavepiece (ref UK-PA-2100024) ('the material') was the subject of inter-company dialogue between Tillotts and Ferring.

Tillotts initiated inter-company dialogue with Ferring on 19 August 2022. Prescribing information included in promotional material for the Pentasa range, both printed and digital, erroneously

stated the dose for adults with acute disease to be 'up to 4 g once daily or in 2-4 divided doses'. This was not in accordance with the marketing authorisations for Pentasa Slow-Release Tablets 500 mg and 1 g and was inconsistent with the summaries of product characteristics (SPCs), both of which stated in Section 4.2 'Acute treatment: Individual dosage of up to 4 g mesalazine once daily or in two or three divided doses'.

Tillotts requested withdrawal of all forms of all materials using the prescribing information as detailed above. In response, Ferring confirmed in their letter dated 2 September 2022 that 'materials which include this Prescribing Information have been withdrawn'. Tillotts contacted Ferring further on 5 September 2022 informing them that several materials using this prescribing information continued to be available on the Ferring UK Hub, and that failure to remove these would result in Tillotts proceeding to make a complaint directly to the PMCPA.

It had come to Tillotts' attention that, at the time of writing to the PMCPA, the material was still in use and could be accessed through the 'view booklet' link on the following page of the Ferring UK Hub, [URL provided]. Tillotts alleged there had either been a failure of Ferring's withdrawal process, or a change in Ferring's commitment to withdraw the material.

Tillotts stated that although the Code did not set a timeline for withdrawal of material, the letter from Ferring confirmed these materials '*have'* been withdrawn, and it was Tillotts' belief that to allow a period of 11 weeks to pass was unacceptable. Tillotts alleged that failure to withdraw the material 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 Ferring 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

Ferring submitted that it was very regretful to have received the PMCPA's letter and wanted to recognise a mistake was made on its part.

Ferring, however, felt obliged to point out that there was a mistake in Tillotts' letter of complaint. The error in Ferring's material was related solely to the information about division of doses (i.e. the document stated that overall dose can be divided to 2–4, it should have said 2–3 doses). There were no errors related to 'once daily administration' as stated in Tillotts' letter. Ferring believed this was important information, given that mesalazine could be taken as one dose and/or divided, at the discretion of the health professional. However, no matter how small the error was, Ferring fully accepted that there was an error on its part and fully took responsibility for it.

Ferring submitted, therefore, that after the inter-company dialogue, it made all efforts to act quickly by recalling the affected material and instructed its digital agency to remove from the Ferring website all material that contained any error. However, although Ferring removed the main source of hyperlinks to its digital assets on the 'Resources' section, it appeared that Ferring was unsuccessful in removing another hyperlink that unfortunately remained active, although hidden due to complexity of the architecture of the website. Following the PMCPA's letter, Ferring realised that it had to take further and more profound steps that would not just

remedy but also prevent any errors of this kind in the future. Ferring submitted that for this reason, it had taken or planned to take the following steps:

1 Done a thorough search and removed the hidden hyperlink and the material from all locations (even from back-end)
2 Agreed to change the practice in terms of division of responsibilities between digital agencies
3 Will conduct a full change of the architecture of its website and prepare mapping to ensure simplicity in adding and removing of digital assets and therefore eliminating any opportunity for this kind of error in the future.

Ferring submitted that it wanted to reassure the PMCPA that safety of its patients was most important to it.

PANEL RULING

The Panel noted Tillotts' allegation that Ferring's failure to withdraw and continued use of a Pentasa leavepiece (UK-PA-2100024) containing incorrect prescribing information, 11 weeks after confirming during inter-company dialogue that it had been 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 Ferring's acknowledgement that it had failed to fully withdraw all hyperlinks to the leavepiece at issue.

The Panel considered that a company's withdrawal process was fundamental to it having adequate control of its active materials and complete and prompt withdrawal was particularly important in relation to materials found to contain incorrect prescribing information.

The Panel considered that Ferring had inadequate control of the material and its failure to fully withdraw the leavepiece, which Ferring acknowledged contained incorrect prescribing information, meant that high standards had not been maintained and a **breach of Clause 5.1** was ruled.

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Complaint received **23 November 2022**

Case completed **24 January 2024**