CASE AUTH/3509/5/21

COMPLAINANT v TILLOTTS

Corporate announcement about the acquisition of Dificlir

An anonymous complainant complained about an advertisement for Dificlir (fidaxomicin) placed by Tillotts Pharma UK Limited. Dificlir was indicated for the treatment of Clostridioides difficile infections.

The complainant alleged that the advertisement, placed in the BMJ, appeared to be the promotion of Dificlir for the treatment of C. difficile infections disguised as a corporate announcement. Prescribing information and adverse event reporting information were not provided.

The detailed response from Tillotts is given below.

The Panel noted that the advertisement was headed 'Tillotts Pharma UK acquire Dificlir (fidaxomicin) for the treatment of Clostridioides difficile infections' and went on to read 'Tillotts are committed to supporting healthcare professionals in improving patient care. With the significant addition of DIFICLIR to our portfolio, we can now extend our support to those diagnosing and treating patients with Clostridioides difficile infections. We provide award-winning educational initiatives, form partnerships and share expertise to meet our aim of consistently delivering quality and value to the NHS'. The Panel noted that the advertisement invited readers to contact medical information for more on Dificlir.

The Panel disagreed with Tillotts' submission that the material was a factual, accurate, informative announcement that included no product claims and was exempt from the definition of promotion. The Panel noted the broad definition of promotion and considered that the material promoted Dificlir; it stated the name of the medicine, its indication, invited readers to contact the company for more information about the medicine and referred to the significant addition of Dificlir to the company's portfolio which meant that it could extend its support to those diagnosing and treating patients with C. difficile infections. The Panel could not see how Tillotts could view the material in question as anything other than promotional material for Dificlir which required prescribing information and a statement on how to report adverse events. No prescribing information or adverse event reporting statement had been provided and the Panel ruled breaches of the Code.

An anonymous complainant, who did not want to be contacted, complained about an advertisement (ref EO-00328, April 2021) for Dificlir (fidaxomicin) placed by Tillotts Pharma UK Limited.

Dificlir was indicated for the treatment of *Clostridioides difficile* infections in adults and children with a body weight of at least 12.5 kg.

COMPLAINT

The complainant alleged that the advertisement, which was placed in the BMJ on 8 May 2021, appeared to be the promotion of Dificlir for the treatment of *C. difficile* infections disguised as a corporate announcement. The complainant stated that the prescribing information and adverse event reporting information, which should have been provided, had not been.

When writing to Tillotts, the Authority asked it to consider the requirements of Clauses 4.1 and 4.9 of the Code.

RESPONSE

Tillotts submitted that the item in question was a corporate announcement referring to the company's acquisition of Dificlir. The purpose of the announcement was to inform health professionals that the ownership of Dificlir had changed, so that should health professionals have an enquiry about availability or any clinical questions, they would know which company to ask. When the announcement was placed, Tillotts intended to take the responsible action of informing the clinical community, not advertising to it. In order to reach the clinical community, the announcement was placed in the BMJ, Clinical Research edition (15 May issue) and other publications (details provided).

Tillotts noted that the term 'promotion' was defined in Clause 1.2 of the Code, and gave specific examples of materials and activities that were not included in this definition, one example being:

> 'factual, accurate, informative announcements and reference material concerning licensed medicines and relating, for example, to pack changes, adverse reaction warnings, trade catalogues and price lists, provided they include no product claims.'

Tillotts submitted that as the announcement was factual, accurate, informative, and was about a licensed medicine that included no product claims, it did not consider that the material was promotional in its content or its intent, and therefore Tillotts did not consider that the prescribing information and the adverse reporting statement were required. Tillotts denied breaches of Clauses 4.1 or 4.9 of the Code.

Tillotts stated that as the material was a corporate announcement, it was examined by signatories to ensure it did not contravene the Code as was required in the supplementary information to Clause 14.3 but was not certified. Details of the signatories were provided.

PANEL RULING

The Panel noted that the material at issue was headed 'Tillotts Pharma UK acquire Dificlir (fidaxomicin) for the treatment of *Clostridioides difficile* infections'; the advertisement went on to read 'Tillotts are committed to supporting healthcare professionals in improving patient care. With the significant addition of DIFICLIR to our portfolio, we can now extend our support to those diagnosing and treating patients with Clostridioides difficile infections. We provide award-winning educational initiatives, form partnerships and share expertise to meet our aim of consistently delivering quality and value to the NHS'. The Panel noted that the advertisement, in prominent red typeface, invited readers to contact medical information via telephone or email for more on Dificlir. The Panel further noted that the advertisement invited the readers to visit a company website '…to see the support we offer to healthcare professionals' and there was a

QR code to scan to learn more about the company; the Panel did not have a copy of the information from the website or the QR code and Tillotts made no submission in that regard. At the bottom of the advisement a number of awards that the company had won was highlighted.

The Panel disagreed with Tillotts' submission that the material was a factual, accurate, informative announcement that included no product claims and was exempt from the definition of promotion. The Panel noted the broad definition of promotion in Clause 1.2 and considered that the material promoted Dificlir; it stated the name of the medicine, its indication, invited readers to contact the company for more information about the medicine and referred to the significant addition of Dificlir to the company's portfolio which meant that it could extend its support to those diagnosing and treating patients with *Clostridioides difficile* infections. The Panel could not see how Tillotts could view the material in question as anything other than promotional material for Dificlir which required prescribing information and a statement on how to report adverse events. No prescribing information had been provided and the Panel ruled a breach of Clause 4.1. Similarly, no adverse event reporting statement had been included as required by the Code and a breach of Clause 4.9 was ruled.

Complaint received **11 May 2021**

Case completed **14 January 2022**