

COMPLAINANT v FERRING

Recertification of material on a website

A complainant, who described him/herself as a concerned UK health professional, complained about the recertification of promotional material available online. The material in question, a supplement entitled 'Trends Urology and Men's Health', commissioned and sponsored by Ferring Pharmaceuticals Ltd included prescribing information for Nocdurna (desmopressin), indicated for the symptomatic treatment of nocturia due to idiopathic nocturnal polyuria in adults. The front cover of the supplement stated that it would be available on the Trends in Men's Health website until December 2017. The complainant doubted that the item had been certified in the last two years since it was not supposed to be being used.

The detailed response from Ferring is given below.

The Panel noted Ferring's submission that it had been unaware of the supplement at issue as it was owned by its European Commercial Organisation ('ECO', originally based in Switzerland but now disbanded). The supplement included the UK prescribing information which included the NHS price and the UK company's address.

The Panel noted that the supplement was available online in a publication which had a European reach which would include the UK; the inclusion of the UK prescribing information meant that the supplement fell within the scope of the UK Code. Although the supplement had been placed by Ferring's European affiliate, it was an established principle, acknowledged by Ferring, that UK companies were responsible for the acts/omissions of overseas parents and affiliates that came within the scope of the Code.

The Panel noted that an agreement, signed by the Ferring ECO, provided that the supplement would be withdrawn from the website six months after the initial posting which Ferring assumed would have been December 2017 as stated on the supplement. Whilst the agreement implied that all copies of the PDF should have been deleted at the same time, this had not been done by the publisher due to an error in its process which had been highlighted by this complaint.

The Panel noted that it was an established principle under the Code that pharmaceutical companies were responsible for third-parties even if that third-party failed to follow instructions from the pharmaceutical company.

The Panel noted Ferring's submission that although the supplement was no longer accessible from a link on the Trends homepage, it had been removed automatically when the hosting period expired, it was still available on the microsite builder when the complaint was made. In addition, readers would still be able to access the PDF if they had saved the link to it in the builder and it could potentially also be found using search terms such as 'nocturia', 'management of nocturia' or 'nocturia Ferring'. The Panel noted that the supplement was therefore available for over two and a half years beyond when it should have been.

The Panel noted that whilst Ferring had been asked to consider a clause related to the certification of material before use, no ruling was made in that regard as the complaint was about the recertification of the material; the complainant noting that the supplement was in use beyond when it should have been. The Code required that material which was still in use was recertified at intervals of no more than two years to ensure that it continued to conform with relevant regulations.

It appeared to the Panel from Ferring's submission and the evidence provided that the supplement had not been certified when it was first published in June 2017 or subsequently, noting it was still available in August 2020 upon receipt of this complaint. A breach of the Code was ruled.

The Panel noted that that in addition to having been badly let down by its affiliate which did not include the UK in the approval process as required by the corporate standard operating procedures, Ferring had also been let down by the third-party agency whose procedures failed to delete the supplement PDF from the microsite builder in December 2017. The Panel noted its comments and rulings above and considered that high standards had not been maintained. A breach of the Code was ruled.

A complainant, who described him/herself as a concerned UK health professional, complained about the recertification of Ferring promotional material available online. The material in question was a supplement entitled 'Trends Urology and Men's Health' which provided a 'Practical approach to diagnosis and management of nocturia'. It was stated on the front cover that the Trends supplement had been commissioned and sponsored by Ferring Pharmaceuticals Ltd and that prescribing information appeared on the back page. It further stated that the supplement would be hosted on the Trends in Urology & Men's Health website (www.trendsinsmenshealth.com) until December 2017.

The prescribing information included on the back page was for Nocurna (desmopressin) which was indicated for the symptomatic treatment of nocturia due to idiopathic nocturnal polyuria in adults.

COMPLAINT

The complainant stated that the promotional material, which he/she had accessed using the link (details provided) should have been withdrawn in December 2017 and should have been available only on the professional website www.trendsinsmenshealth.com but was still currently available. The complainant also stated that he/she doubted that the item had been certified in the last two years since it was not supposed to be being used.

When writing to Ferring, the Authority asked it to consider the requirements of Clauses 9.1, 14.1 and 14.5 of the Code.

RESPONSE

Ferring submitted that the supplement in question (copy provided) was removed from the publisher's microsite builder webpage within a day of receiving this complaint. Ferring submitted that the supplement had not been used by the UK affiliate in any way or in any engagements with UK health professionals; it might have been used in other European jurisdictions. The intended geographic audience was European in scope. Ferring noted that the approval code in the prescribing information (ref NOQ/2109/2016/UK) related to the UK approval of the prescribing information and not to the supplement.

Ferring explained that the material was owned by its European Commercial Organisation ('ECO', based in Switzerland), which had now been disbanded, and by an employee who was

no longer with Ferring. Therefore, some of the background to purpose and process was unavailable. Ferring stated that its UK affiliate was not aware of the supplement or that it had been posted on the Trends in Men's Health website, the website associated with the 'Trends in Urology and Men's Health' publication. Ferring understood that 'Trends in Men's Health' was selected by the Ferring ECO due to the authors' affiliation with it and its European reach.

Regardless, Ferring was fully aware that it was responsible under the Code for the activities of its ex-UK affiliates that had an impact on UK health professionals. Ferring submitted that, as such, the following response was as accurate and transparent as possible, considering that the ECO was no longer in place and the only person who worked on the supplement had now left Ferring.

The supplement in question was authored by leading specialists in nocturia from across Europe and owned by Ferring's ECO. As stated in the introduction, the supplement aimed to 'provide primary care physicians with straightforward, practical recommendations and tools for [nocturia] diagnosis and treatment, as well as advice on when specialist referral may be required'. Therefore, it was intended to be a balanced, educational publication aimed at primary care physicians across Europe. Full editorial control remained with the authors.

Ferring explained that microsite builders were used to build content and microsites were used to host content for a main website (in this case www.trendsinmenshealth.com) and in the case of the microsite, the content was accessed via a link from the main website.

For the material in question, the microsite builder was used to generate the digital version of the supplement, from which the supplement PDF should have been deleted in December 2017 when it was also removed from the microsite (the statement from the publishers appears below).

Ferring assumed that the supplement was first published on the microsite in June 2017 and removed in December 2017. The publisher was unable to confirm this as the document had been deleted from both.

Ferring submitted that the agreement (signed by the Ferring ECO in April 2017) provided that the material in question would be withdrawn from the 'Trends in Men's Health' website after six months from the initial posting. This implied that all copies of the PDF would also have been deleted once the link from the 'Trends' website was and would be removed from the microsite builder and the microsite.

With regard to the supplement still being available online in August 2020 on the microsite builder page, whilst the link to the microsite had been removed from the 'Trends in Men's Health' website, the supplement was still available on the microsite builder, the PDF of which should have also been deleted in December 2017, which was not.

Upon further investigation, it appeared that the supplement was accessible via a web search for related words and phrases such as 'nocturia', 'management of nocturia' or 'nocturia Ferring'.

Unfortunately, Ferring was not aware of the supplement posting and hence was not monitoring it to ensure that it was not available elsewhere on the internet. Ferring provided a statement from the publisher, highlighting the flaws in its processes as follows:

'This is an outline of what has happened:

- The PDF was hosted within our microsite builder in WordPress

- Users accessed the PDF by clicking a link embedded in a feature box on the Trends home page. No registration or password was required for this project as the intention was for users to have no restrictions to access
 - NB: only the admin access to the microsite builder is password protected by default. File access is only protected on request.
- The feature box was removed automatically from the home page when the hosting period expired. The PDF was therefore no longer discoverable via the embedded link or via the search box on the Trends home page
- However, readers would still be able to access the PDF if they had saved the link to it in the builder; it could potentially also be discoverable via search engines

Your correspondence has actually raised awareness of an error in our processes. The automated removal of the feature box should be followed up by someone navigating to the builder and making sure that the hosted file is deleted from there.

I apologise for the fact that this did not happen and that the file remained accessible for so long beyond its expiry date. Please be assured that we will be amending our workflow documents to make sure this doesn't happen again.'

Ferring submitted that after investigation, it was clear that it was not possible to navigate from the microsite builder homepage to the supplement in question as it was password protected. As mentioned above, it appeared that only by typing related terms into a browser that the supplement could be accessed on this microsite builder.

This had now been taken down and was no longer accessible on the microsite builder.

With regard to company processes for reviewing material to ensure that it was either withdrawn or recertified as required, Ferring submitted that all product and disease related materials for use in the UK were reviewed by medical affairs and the commercial team for accuracy and compliance and were certified by two final signatories, that was a medical practitioner (UK registered) and a commercial signatory in accordance with the Code. Administrators were notified when previously certified materials required review after a two-year period of original certification and these were circulated for re-review and re-certification.

Ferring submitted that UK standard operating procedures (SOPs) (copies provided) were in place for certification of approvable materials and the withdrawal of material; all personnel involved in these processes were trained on the SOPs.

Ferring also gave details of its corporate SOPs which covered global (and therefore European) activities. The corporate certification SOPs (CS-10237, Approval of therapy area and product specific promotional and non-promotional marketing material (copy provided)) version 2 (effective from 16/06/2014) and version 4 (effective from 04/11/2017) were effective at the time and CS-10237 v4 stated the same as the currently active SOP:

'At all stages of development, it is the responsibility of the Global Strategic Brand Leader and/or Global Medical Director to ensure the material complies with (among others): Local laws, regulations and industry codes of specific interest (otherwise this responsibility falls under each Group Entity prior to release of materials in their own country).'

The supplement in question was owned by the Ferring ECO (which no longer existed), in collaboration with the publisher, and without the involvement or input of the Ferring UK affiliate. Therefore, it was covered by corporate SOPs. In this instance, Ferring in the UK was

not involved due to a failure to properly apply Ferring's corporate SOPs. This had been communicated as such to Ferring's global colleagues to ensure there was no repetition of these events.

PANEL RULING

The Panel noted Ferring's submission that the supplement at issue was owned by its European Commercial Organisation ('ECO', based in Switzerland), which had now been disbanded. The Panel did not know exactly when this disbandment had occurred. The Panel noted Ferring's submission that the UK affiliate was not aware of the supplement or that it had been posted on the Trends in Men's Health website which was associated with the 'Trends in Urology and Men's Health' publication. The Panel noted Ferring's submission that 'Trends in Men's Health' had been selected by the Ferring ECO due to, *inter alia*, its European reach. The Panel further noted that the journal supplement included the UK prescribing information (ref NOQ/2109/2016/UK) which included the NHS price and UK company's address. There did not appear to be any reference number related to the supplement *per se*.

The Panel noted that the supplement was available online in a publication which had a European reach which would include the UK. Further, the inclusion of the UK prescribing information on the supplement as noted above meant that it fell within the scope of the UK Code. The Panel further noted that although the supplement had been placed by Ferring's European affiliate, it was an established principle that UK companies were responsible for the acts/omissions of overseas parents and affiliates that came within the scope of the Code. This was acknowledged by Ferring.

The Panel noted that an agreement (signed by the Ferring ECO in April 2017) was in place which provided that the material in question would be withdrawn from the 'Trends in Men's Health' website after six months from the initial posting which Ferring assumed would have been December 2017 as stated on the supplement. The Panel noted Ferring's submission that whilst the agreement implied that all copies of the PDF should have been deleted in December 2017, this had not been done by the publisher due to an error in its process which had been highlighted by this complaint.

The Panel noted that it was an established principle under the Code that pharmaceutical companies were responsible for third parties even if that third party failed to follow instructions from the pharmaceutical company.

The Panel noted Ferring's submission that although the supplement was removed in so much as it was no longer accessible from a link embedded on the Trends homepage which according to the publisher had been removed automatically when the hosting period expired, the supplement was still available on the microsite builder at the time of the complaint. In addition, readers would still be able to access the PDF if they had saved the link to it in the builder and it could potentially also be discoverable via search engines using words and phrases such as 'nocturia', 'management of nocturia' or 'nocturia Ferring'. The Panel noted that the supplement was therefore available for over two and a half years beyond when it should have been.

The Panel noted that whilst the case preparation manager had raised Clause 14.1 there did not appear to be an allegation in relation to the supplement not being certified prior to its initial publication in June 2017; the complaint was regarding the recertification of the material noting that it was in use beyond when it should have been. The Panel therefore made no ruling in relation to Clause 14.1.

The Panel noted that Clause 14.5 stated that the certificate for promotional material must certify that the signatory had examined the final form of the material to ensure that in his/her

belief it was in accordance with the requirements of the relevant regulations relating to advertising and this Code, was not inconsistent with the marketing authorization and the summary of product characteristics and was a fair and truthful presentation of the facts about the medicine. Clause 14.5 further required that material which was still in use was recertified at intervals of no more than two years to ensure that it continued to conform with the relevant regulations relating to advertising and the Code.

The Panel noted Ferring's submission that Ferring UK was not involved in the approval of the supplement at issue due to a failure of Ferring global to properly apply Ferring's corporate SOPs. The Panel noted that the supplement did not include a reference number other than that within the UK prescribing information and no certificate had been provided. It appeared to the Panel from Ferring's submission and the evidence provided that the supplement had not been certified when it was first published in June 2017 or subsequently noting it was still available in August 2020 upon receipt of this complaint. The Panel therefore ruled a breach of Clause 14.5.

The Panel noted that the supplement, which appeared not to have been certified at the outset, was available for over two and a half years longer than it should have been and that in addition to having been badly let down by its affiliate which did not include the UK in the approval process as required, Ferring had also been let down by the third-party agency whose procedures failed to delete the PDF of the supplement from the microsite builder in December 2017. The Panel noted its comments and rulings above and considered that high standards had not been maintained. A breach of Clause 9.1 was ruled.

Complaint received **11 August 2020**

Case completed **29 January 2021**