

CASE AUTH/3310/2/20

EX-EMPLOYEE v INDIVIOR

Article in online trade journal

An anonymous, non-contactable ex-employee of Indivior UK Limited, complained about an article which had appeared in the online version of Pharmaceutical Market Europe (PME), PMLiVE, December 2019. The article which was entitled 'As the opioid crisis grabs the headlines, the search for safe treatments continues' recorded an interview with an Indivior senior executive.

The complainant alleged that the online article, which was easily accessible by the medical profession and the public, was veiled as an industry piece but was in breach of the Code as it promoted unlicensed medicines.

The complainant alleged that there were a number of claims for unlicensed medicines and he/she assumed that the article was intended as part of a pre-marketing campaign. The article distribution was wide and not limited to industry.

The complainant alleged that the content of the article was disguised as informative but the details gave the impression of impending launch and therefore promotion with the inclusion of brand names and claims. These were made with a blatant disregard for the Code. The complainant alleged that such conduct was unacceptable and brought discredit to, and reduced confidence in, the pharmaceutical industry.

The detailed response from Indivior is given below.

The Panel considered that it was key to first note the context in which the article at issue had been published and then to note any use of the article by Indivior.

The Panel noted that PME was a trade journal aimed at senior/chief executives in the pharmaceutical industry; the PME media pack referred to the publication as 'a trusted source of information for decision makers working in the pharma and biotech sectors' and stated that over half of its 25,000 circulation (print and digital) went to those in the industry and the rest went to those in the service sector. The journal was not aimed at the public.

In the Panel's view, trade journals existed to, amongst other things, discuss industry concerns and product innovations etc and it was important that they were able to do that. The article at issue had not been commissioned by Indivior but clearly the company had cooperated with the journalist who had written it. The company had agreed to the interview on the basis that the resulting article would instil greater awareness of the broader public health issues surrounding opioid dependence and inform Indivior's peer group of the company's leadership in addressing the opioid addiction and wider industry issues concerning efficiency in research and development and improvement of the

access to new treatments. The company had not acted to increase awareness of the issues raised, or of its products, amongst health professionals or the public and, given the distribution of PME, would have no reasonable expectation of the article doing that. The Panel further noted Indivior's submission that once published, it had not circulated or distributed the article outside the company and that those employees who had received a copy of the article were asked not to distribute it further or post it on any social media. The Panel considered that although it might be possible for a health professional or a member of the public to find the article via an Internet search, in doing so he/she would have accessed ('pulled') a publication solely intended for pharmaceutical industry executives.

The Panel considered that given the context in which the article at issue appeared ie in a journal aimed at executives in the pharmaceutical industry or those in the service sectors, and that Indivior had not distributed the article outside of the company, it did not promote prescription only medicines to the public and in that regard no breach of the Code was ruled. The Panel considered that as PME was not aimed at the public, the clause relating to information about prescription only medicines made available to the public was not relevant and so no breach of that clause was ruled.

Given its rulings above the Panel considered that there had not been a failure to maintain high standards and ruled no breach of the Code.

Clause 2 was a sign of particular censure and was reserved for such use. The Panel noted its rulings of no breach above and consequently ruled no breach of Clause 2.

An anonymous, non-contactable individual, who described him/herself as an ex-employee of Indivior UK Limited, complained about an article which had appeared in the online version of Pharmaceutical Market Europe (PME), PMLIVE, December 2019. The article recorded an interview with an Indivior senior executive. The article was entitled 'As the opioid crisis grabs the headlines, the search for safe treatments continues'.

COMPLAINT

The complainant alleged that the article in question was veiled as an industry piece but was in breach of the Code as it promoted unlicensed medicines. The complainant was unsure if the article had been published beyond the Internet in other versions of the journal. The online article was easily accessible by the medical profession and the public.

The complainant alleged that there were a number of either direct or inferred claims for medicines, none of which, to his/her knowledge were licensed in the UK or Europe ie Suboxone film (buprenorphine and naloxone sublingual film) and Sublocade (long-acting buprenorphine injection) for opioid addiction and the long-acting injectable Perseris (risperidone) for schizophrenia. The complainant assumed that the article was intended as part of a pre-marketing campaign. The article distribution was wide and not limited to industry.

The complainant alleged that the content of the article was disguised as informative but the details gave the impression of impending launch and therefore promotion with the inclusion of brand names and claims. These were made with a blatant disregard for the Code. The complainant alleged that such conduct was unacceptable and brought discredit to, and reduced confidence in, the pharmaceutical industry.

When writing to Indivior, the Authority asked it to consider the requirements of Clauses 2, 9.1, 26.1 and 26.2 of the Code.

RESPONSE

Indivior noted that the article contained certain statements obtained from an interview between the author and Indivior's senior executive. The article sought to address the global public health issues surrounding opioid dependence and how the industry should 'create safe and effective drugs to deal with, rather than inflame, a crisis' according to the author. The author then went on to address the need for industry to develop new medicines more efficiently to improve access to treatments. These were current issues that the industry and the healthcare systems were grappling with.

Indivior submitted that PME was a monthly print and digital title written by experienced healthcare journalists and high-profile pharmaceuticals and healthcare experts. The journal provided insights and offered solutions to the issues relevant to industry leaders who were the target audience of the journal. Similarly to many other sector-specific journals, PME regularly engaged its journalists to interview industry leaders to share the individual company's ethos and ambitions.

Indivior submitted that the article was initiated and independently authored by the journalist; it was not initiated, sponsored or commissioned by Indivior. This was not an activity undertaken by Indivior or with its authority on its behalf. The journalist was not paid by Indivior to prepare the article. Indivior explained that it was contacted by a communications agency after receiving an unsolicited request from a named healthcare journalist to interview one of its senior executives. In its request, the communications agency stated: 'we have an opportunity with [named author], UK freelancer, who is writing an article for Pharmaceutical Market Europe (PME) magazine on the topic of opioid addiction in Europe. He would really like to interview [named Indivior employee] as a senior executive of a company that is helping to address the issue and hear about Indivior's ethos and ambition. It is likely to be a double-page spread and the opportunity will be great for Indivior to raise their profile and demonstrate leadership in this space'.

For transparency, Indivior noted that in September 2019 it reached out to four UK healthcare journalists to attend the Lisbon Addictions 2019 Conference in order to understand whether they would require support to attend such a conference, with the view to enhancing their education and knowledge. The conference was organised to discuss the multidisciplinary issues about addictions that might influence the future directions of policy, practice and science in the treatment and management of addictions, opioid disorder and the related behavioural disorders. The named author in this case was one of those contacted but he declined. Ultimately Indivior supported only one journalist. No support, or any other transfer of value was provided to any other party, including the named author in this case.

Indivior stated that opioid use disorder was on the rise globally with much coverage in both the healthcare and public media. In that context, it was understandable that a healthcare journalist would want to conduct an interview with a company which was a recognised leader in the fight against opioid use disorder.

Indivior stated that it did not contribute towards the preparation of the manuscript or any questions raised by the journalist. The article was written and produced by the author based, in part, on the interview with the Indivior senior executive. Neither Indivior nor its senior executive contributed to, or controlled, the questions put forward by the journalist or had editorial, publication or distribution control of the published article (online or in print).

Indivior stated that the article was not aimed at the public; PME was an industry trade publication aimed at senior executives or leaders of the industry. Information from the PME (print publication) media pack stated 'Pharmaceutical Market Europe (PME) is a trusted source of information for decision makers working in the pharma and biotech sectors – helping them to keep abreast of the big issues in healthcare and put them into context'. It was with this knowledge and understanding that Indivior and its senior executive agreed to provide the interview.

Additionally, Indivior agreed to its senior executive being interviewed by the named author of PME on the understanding that the resultant article would instil greater awareness of the broader public health issues surrounding opioid dependence, which was now recognised as a global crisis by the coalition of regulators and healthcare policymakers, and that it would inform Indivior's peer group of the company's leadership in addressing the opioid addiction and wider industry issues concerning efficiency in research and development and improvement of the access to new treatments.

PME was distributed to over 25,000 subscribers, of which half worked in pharmaceuticals and the others were agencies (vendors for the pharmaceutical industry). The journal had a global reach (rest of World (38%), EU (28%), USA (22%) and UK (12%)). PMLiVE (online) publications had over 113,000 unique users. Users had to subscribe free to receive email notifications. PME only catered to pharmaceuticals and agencies serving the pharmaceutical industry.

Indivior noted that, as a general matter, the advertising rules regulated canvassing activity or inducement with the effect of promoting prescription, supply and use of a medicine. The rules, however, did not seek to regulate the behaviour of the public to pull information from publicly available sources. The public might conceivably use search engines to look for key words, 'opioids' or 'opioid addiction' or in combination with 'Indivior'. However, such a search had not identified the article in question. In any event, management of the external communication of this published article was a matter for PME and not Indivior.

Indivior stated that it had not proactively or reactively distributed the publication (either online or in print) outside of the organisation. Indivior had no control over how PME distributed its published articles and this was a matter for its editorial board. Indivior stated that once published, the article was circulated internally, for information only, to twenty six people within EUCAN (Europe and Canada) including the senior executive interviewed, employees within medical, marketing and general managers and on the same day of publication, in a cover note to all internal recipients, Indivior's senior executive stated 'please do not distribute further this article and do not post it on any social media. If you receive any inquiries or questions from journalists in your country, please refer them to Chief Corporate Affairs & Communications Director for her to determine the best course of action'.

Indivior considered that the complainant's allegations were only valid and within the scope of the Code if the article constituted promotion within the meaning of the Code. Indivior did not accept

that the article was promotional in the sense of the Code, ie, an activity undertaken by a pharmaceutical company or with its authority which promoted the administration, consumption, prescription, purchase, recommendation, sale, supply or use of its medicines.

As explained above, the article was written by the third-party journalist based in part on an interview with an Indivior senior executive to discuss the global public health related issues. The article was not prepared at Indivior's request and it was not commissioned by the company or with its authority. For these reasons there was, in Indivior's view, no breach of the Code.

Indivior did not accept that Clause 26.1 had been breached. In addition to the factual assessment provided above, the key points in support of Indivior's assessment were:

- The article was not initiated, commissioned or otherwise controlled by Indivior.
- If read in a proper context, the article was not intended to promote prescription only medicines and it did not convey the effect of promoting the prescription only medicines. As explained above, the article, written by the third party journalist, sought to address the broader public health issues that might impact on industry-wide policy to improve efficiency in research and development and patient access to medicines.
- The editorial board of PME determined the target audience and not Indivior and hence the distribution and publication of the articles contained in each issue of the journal. As explained, the target audience was the senior leadership and executives of industry.
- Indivior did not know whether the PME editors decided to make all of its articles publicly available through an electronic domain. As Indivior had no editorial control, this was a matter for PME but it appeared that PME editorial policy permitted articles of each issue of the journal to be published in a digitalised format.

Indivior submitted that for these reasons and those already mentioned, there was no basis to suggest that Clause 26.1 was breached.

With regard to Clause 26.2, Indivior stated that:

- The responses provided by its senior executive to the questions raised by the journalist were factual, balanced and represented the current state of play of the global public health issues concerning opioid addiction and access to treatment.
- It was evident that references to the specifically named medicines were not part of the interview conducted by the journalist with Indivior's senior executive – rather they were made as part of the authorship of the journalist. These references, on an objective assessment, did not encourage members of the public to ask their health professional to prescribe a specific prescription only medicine.

For the above reasons, Indivior denied a breach of Clause 26.2.

Indivior submitted that there was no proper basis to allege a breach of Clause 9.1 in relation to the company's involvement in the interview.

- Indivior was fully committed to complying with laws, regulations and industry codes of conduct through established in-house policies and procedures.

- A publication prepared by a third party (which had no contractual arrangement or link with Indivior) did not fall within the types of communication that would trigger an internal certification according to the Code. Even though the author gave Indivior a copy of the draft manuscript for feedback, the review was restricted to ensuring factual and scientific accuracy. Given the article was authored by a healthcare journalist, it would not be appropriate for Indivior to make any suggestion that sought to influence substantially the authorship.

Indivior denied a breach of Clause 9.1.

Indivior did not accept that Clause 2 applied, particularly given that the publication was authored by a third party who had no contractual arrangement or link with the company. As explained above, the publication was not commissioned by Indivior or written with the company's authority. It would be disproportionate for Indivior to be held accountable for a third party's activity. In any event, there was no basis to suggest Clause 2 was breached.

In any case, when considering the article in a proper context, the content did not bring discredit upon, or reduce confidence in, the pharmaceutical industry. Raising awareness of the global scourge of opioid addictions ought to be part of the concerted effort with the relevant stakeholders including governmental and non-governmental organisations. Similarly, an expressed view of improving efficiency in research and development and patient access did not bring discredit upon, or reduce confidence in, the pharmaceutical industry. Indeed, this represented the industry-wide efforts of ensuring 'patient centricity' by placing patients at the centre of healthcare delivery, which was also the over-arching objective of the NHS Constitution.

Indivior was very disappointed that its objective to raise awareness around opioid use disorder and its mission to battle against such disease to the pharmaceutical industry via a trade journal was perceived by the purported ex-employee 'as part of pre-marketing campaign'. In the context described Indivior strongly disagreed with this perception and it denied a breach of Clause 2.

PANEL RULING

The Panel noted that the complainant was anonymous and non-contactable. The Constitution and Procedure stated that anonymous complaints would be accepted, but that like all other complaints, the complainant had the burden of proving his/her complaint on the balance of probabilities. All complaints were judged on the evidence provided by the parties. The complainant could not be contacted for further information.

The complainant alleged that the online article was easily accessible by health professionals and the public and that distribution of the article was wide and not limited to the industry. The complainant had provided no information to support these allegations. The complainant had further alleged that the article promoted unlicensed medicines. The case preparation manager raised Clauses 26.1 and 26.2.

The Panel noted that Clause 26.1 stated that prescription only medicines must not be advertised to the public. Clause 26.2 stated that information about prescription only medicines which was made available to the public either directly or indirectly must be factual and presented in a balanced way. It must not raise unfounded hopes of successful treatment or be

misleading with respect to the safety of the product. Statements must not be made for the purpose of encouraging members of the public to ask their health professional to prescribe a specific prescription only medicine.

The Panel considered that it was key to first note the context in which the article at issue had been published and then to note any use of the article by Indivior.

The Panel noted that PME was a trade journal aimed at senior/chief executives in the pharmaceutical industry; the PME media pack referred to the publication as 'a trusted source of information for decision makers working in the pharma and biotech sectors' and stated that over half of its 25,000 circulation (print and digital) went to those in the industry and the rest went to those in the service sector. The journal was not aimed at the public.

In the Panel's view, trade journals existed to, amongst other things, discuss industry concerns and product innovations etc and it was important that they were able to do that. The article at issue had not been commissioned by Indivior but clearly the company had cooperated with the independent healthcare journalist who had written the article. The company had agreed to the interview on the basis that the resulting article would instil greater awareness of the broader public health issues surrounding opioid dependence and inform Indivior's peer group of the company's leadership in addressing the opioid addiction and wider industry issues concerning efficiency in research and development and improvement of the access to new treatments. The company had not acted to increase awareness of the issues raised, or of its products, amongst health professionals or the public and, given the distribution of PME, would have no reasonable expectation of the article doing that. The Panel further noted Indivior's submission that once published, it had not circulated or distributed the article outside the company and that those employees who had received a copy of the article were asked not to distribute it further or post it on any social media. The Panel considered that although it might be possible for a health professional or a member of the public to find the article via an Internet search, in doing so he/she would have accessed ('pulled') a publication solely intended for pharmaceutical industry executives.

The Panel considered that given the context in which the article at issue appeared ie in a journal aimed at executives in the pharmaceutical industry or those in the service sectors, and that Indivior had not distributed the article outside of the company, it did not promote prescription only medicines to the public and in that regard no breach of Clause 26.1 was ruled. The Panel considered that as PME was not aimed at the public, Clause 26.2 was not relevant and so no breach of that clause was ruled.

Given its rulings above and the Panel considered that there had not been a failure to maintain high standards and ruled no breach of Clause 9.1.

Clause 2 was a sign of particular censure and was reserved for such use. The Panel noted its rulings of no breach above and consequently ruled no breach of Clause 2.

Complaint received 17 February 2020

Case completed 21 May 2020