CASE AUTH/2529/9/12

ANONYMOUS/DIRECTOR v VIFOR

Breach of undertaking

An anonymous GP complained about advertisements issued by Vifor global which had been the subject of a voluntary admission by Vifor Pharma, Case AUTH/2473/1/12.

In Case AUTH/2473/1/12, Vifor voluntarily admitted that advertisements had not been certified prior to publication and the Panel ruled a breach of the Code. During its consideration of the case, however, the Panel further noted that, as acknowledged by Vifor in subsequent correspondence, the advertisements featured the strapline 'Mastering the art of iron therapy' which had been ruled in breach in Case AUTH/2423/7/11. However, as Vifor's initial voluntary admission only related to a lack of certification, the Panel could make no ruling with regard to the possible breach of undertaking. Given the importance of complying with undertakings, Vifor was informed of the position and the matter was noted in the case report. Having read that case report, the complainant now asked for the breach of undertaking to be investigated.

As the complaint concerned an alleged breach of undertaking it was taken up by the Authority in the name of the Director as the Authority was responsible for ensuring compliance with undertakings.

The detailed response from Vifor is given below.

The Panel noted that in its consideration of Case AUTH/2473/1/12 it had been extremely concerned to note that the advertisements at issue featured the strapline 'Mastering the art of iron therapy' which was ruled in breach in Case AUTH/2423/7/11. Vifor had accepted the ruling in that case and provided the relevant undertaking and assurance. The advertisements with the same strapline were therefore potentially in breach of that undertaking. The Panel noted that in Case AUTH/2473/1/12 Vifor had voluntarily brought to the Authority's attention advertisements containing the same strapline but had only admitted a breach of the Code with regard to lack of certification. The Constitution and Procedure did not allow the Panel to consider matters which were not subject of a complaint or a voluntary admission and nor was there any mechanism under which it could instigate a fresh complaint. The Panel could only point the matter out to the company concerned and note it in the case report. The Panel's comments in this regard appeared to have prompted the complaint now at issue. It was very unusual to receive a subsequent complaint about such a matter.

The Panel considered that the repeated use of the claim 'Mastering the art of iron therapy' breached the undertaking given in Case AUTH/2423/7/11 and in that regard high standards had not been maintained. Breaches of the Code were ruled.

The Panel noted the importance of undertakings and considered that failure to comply with the undertaking and assurance previously given in Case AUTH/2423/7/11 had brought discredit upon and reduced confidence in the pharmaceutical industry. The Panel ruled a breach of Clause 2.

A non-contactable complainant who described themselves as a general practitioner complained about advertisements issued by Vifor global which had been the subject of a voluntary admission by Vifor Pharma Limited, Case AUTH/2473/1/12.

In Case AUTH/2473/1/12, Vifor voluntarily admitted that advertisements, published in three specialist European journals, had not been certified prior to publication and the Panel subsequently ruled a breach of Clause 14.1 (it was established that the journals were such that advertisements within them came within the scope of the UK Code). During its consideration of the case, however, the Panel further noted that, as acknowledged by Vifor in subsequent correspondence, the advertisements featured the strapline 'Mastering the art of iron therapy' which had been ruled in breach of Clause 7.2 in Case AUTH/2423/7/11. However, as Vifor's initial voluntary admission only related to a breach of the Code with regard to certification, the Panel could make no ruling with regard to the possible breach of undertaking. Given the importance of complying with undertakings, Vifor was informed of the position and the matter was noted at the end of the published case report. Having read that case report, the complainant now asked for the breach of undertaking to be reinvestigated.

As the complaint concerned an alleged breach of undertaking it was taken up by the Authority in the name of the Director as the Authority was responsible for ensuring compliance with undertakings.

COMPLAINT

The complainant explained that he/she was introduced to the PMCPA website by a medical representative; he/she sometimes read published cases, which he/she found very interesting. The complainant submitted that he/she was surprised by the ruling in Case AUTH/2473/1/12 wherein Vifor made a voluntary admission and was, in the complainant's opinion, treated leniently and ruled in breach of Clause 14.1 only.

The complainant considered that Vifor should also have been ruled in breach of Clauses 25, 9.1 and 2. The complainant was sure that if the advertisement at issue had been placed by a UK company, the PMCPA

would have ruled it in breach of the above clauses. The complainant queried whether the ruling of a breach of Clause 14.1 was because the advertisement in question was placed by the global part of the UK company although, if that was the case, the PMCPA contradicted its own statement in the published case report about it being 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.

RESPONSE

Vifor explained that it took the Panel's rulings extremely seriously and assured the PMCPA that it was committed to abiding by the Code at all times. Vifor knew the importance of complying with undertakings and the seriousness of the consequences of such a breach for both the company involved and the reputation of the industry as a whole.

Vifor acknowledged that the publication of the advertisements referred to in Case AUTH/2473/1/12 amounted to a breach of the undertaking given in Case AUTH/2423/7/11 and were therefore in breach of Clause 25. Vifor strongly believed in self-regulation hence the voluntary admission in Case AUTH/2473/1/12 as to the failure to certify. Vifor regretted that due to its lack of experience in self-reporting, the breach of Clause 25 was not specifically outlined in its initial letter to the PMCPA and was therefore not formally considered as part of Case AUTH/2473/1/12. Vifor noted, however, that although this was inadvertently not specifically mentioned in its initial letter, a full and frank disclosure acknowledging the breach of Clause 25 in line with the spirit of the Code was included in the follow up letter to the PMCPA in February 2012 prior to the Panel making its ruling. Vifor had now noted the full process for any potential future instances requiring the self-reporting of breaches.

Vifor stated that it had made every effort to ensure compliance with the Authority's ruling in Case AUTH/2423/7/11. All UK materials were withdrawn immediately and its global colleagues were notified that the relevant claims could no longer be used.

Vifor gave details of the steps undertaken to ensure its global colleagues were aware of the relevant ruling as follows:

- August 2011: Notified senior global colleagues of the outcome of the case on the same day the outcome was received by Vifor. This email expressly stated that the claim 'Mastering the art of iron therapy' had been ruled in breach of the Code.
- August 2011: Obtained confirmation of receipt from one of the global colleagues who requested that this topic be discussed at the next global medical directors' meeting.
- September 2011: Case discussed at medical directors' meeting.
- December 2011: Global team trained on ABPI Code.
- February 2012: Training given to global team on inspection training and approval of materials.
- March 2012: Presentation given by senior UK manager to the European Affiliates Board.
- April 2012: Presentation given to global executive operations meeting (Vifor's operational leadership group).

Vifor therefore believed that the actions taken in the UK and globally to notify colleagues of the original undertaking in Case AUTH/2423/7/11, and its self-reporting in Case AUTH/2473/1/12, illustrated that the company took all possible steps to comply and did not fail to maintain high standards. Vifor submitted that it had not breached Clauses 9.1 or Clause 2.

PANEL RULING

The Panel noted that in its consideration of Case AUTH/2473/1/12 it had been extremely concerned to note that the advertisements at issue featured the strapline 'Mastering the art of iron therapy' which was ruled in breach of Clause 7.2 of the Code in Case AUTH/2423/7/11. Vifor had accepted the ruling in that case and provided the relevant undertaking and assurance. Subsequent placement of the advertisements with the same strapline was therefore potentially in breach of the undertaking. The Panel noted that in Case AUTH/2473/1/12 Vifor had voluntarily brought to the Authority's attention advertisements containing the same strapline but had only admitted a breach of the Code with regard to lack of certification. The Constitution and Procedure did not allow the Panel to consider matters which were not subject of a complaint or a voluntary admission and so it had been unable to rule upon the potential breach of undertaking which it had noted and nor was there any mechanism under which it could instigate a fresh complaint. The only option available to the Panel was to point the matter out to the company concerned and note it in the case report. It was very unusual to receive a subsequent complaint about such a matter.

In Case AUTH/2473/1/12 the Panel had noted that a breach of undertaking was a serious matter and it advised Vifor of its concerns which were also noted in the final paragraph of the case report published on the Authority's website in May 2012. The Panel did not refer to any clauses of the Code. The Panel noted that it was this final paragraph of the case report which had appeared to have prompted the complaint now at issue with the complainant citing Clauses 2, 9.1 and 25.

The Panel noted that although the advertisements at issue had been placed by the global organisation in specialist European journals, it was established in Case AUTH/2473/1/12 that advertisements placed in those journals came within the scope of the UK Code. Further, 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.

Turning to Case AUTH/2529/9/12, the Panel noted the repeated use of the claim 'Mastering the art of iron

therapy' and considered that such use breached the undertaking given in Case AUTH/2423/7/11. A breach of Clause 25 was ruled. In that regard high standards had not been maintained. The Panel ruled a breach of Clause 9.1.

The Panel noted the importance of undertakings and considered that failure to comply with the undertaking and assurance previously given in Case AUTH/2423/7/11 had brought discredit upon and reduced confidence in the pharmaceutical industry. The Panel ruled a breach of Clause 2.

Complaint received **17 September 2012**

Case completed **24 October 2012**