

# VOLUNTARY ADMISSION BY VIFOR

## Ferinject advertisement

Vifor Pharma advised the Authority that three advertisements for Ferinject (ferric carboxymaltose) solution for injection/infusion, placed in international journals by its global colleagues, had not been certified in accordance with the Code. Ferinject was indicated for the treatment of iron deficiency when oral iron preparations were ineffective or could not be used.

In accordance with Paragraph 5.6 of the Constitution and Procedure for the Prescription Medicines Code of Practice Authority, the Director treated the matter as a complaint.

The detailed response from Vifor is given below.

The Panel noted Vifor's submission that the content of each journal was produced in the UK for a European and international circulation. Vifor submitted that the editorial offices for each of the three journals was managed from, and the journals were typeset and printed in, the UK. The Panel thus considered that the advertisements in the journals at issue fell within the scope of the Code.

The Panel noted that although the advertisements for Ferinject had been placed by Vifor's global office, 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. The advertisements had not been certified in accordance with the UK Code. The Panel thus ruled a breach of the Code in relation to each advertisement, as acknowledged by Vifor.

Vifor Pharma Limited made a voluntary admission in relation to three advertisements for Ferinject (ferric carboxymaltose) solution for injection/infusion placed in international journals by its global colleagues. Ferinject was indicated for the treatment of iron deficiency when oral iron preparations were ineffective or could not be used.

In accordance with Paragraph 5.6 of the Constitution and Procedure for the Prescription Medicines Code of Practice Authority, the Director treated the matter as a complaint.

### COMPLAINT

The three advertisements at issue were organised by Vifor's global colleagues and were signed off globally, but were not certified in accordance with the Code. The advertisements were placed in the following journals:

- European Journal of Heart Failure, January 2012 (artwork placed 28 November 2011)
- European Heart Journal, December 2011 (artwork placed 3 November 2011)

- NDT (Nephrology Dialysis Transplantation), December 2011 (artwork placed 11 November 2011)

Vifor submitted that the journal content was produced in the UK for European and international circulation including UK circulation. The journals were not aimed exclusively at a UK audience, however they were printed in English and produced by a UK publisher.

Vifor submitted that as soon as the advertisements came to its attention it arranged meetings with its global colleagues. The global teams were trained on the Code in December 2011 and were now well aware of their responsibilities in certifying advertisements placed in journals that were produced, published and directed towards the UK. The advertisements in question were placed before the December training session.

Vifor submitted that these corrective actions had been taken to avoid a repetition of such instances. In addition processes had been revisited to ensure there were correct procedures to ensure that global teams followed the certification process when they initiated these advertisements in the future.

When writing to Vifor, the Authority asked it to respond in relation to Clauses 1.1 and 14.1 of the Code and drew attention to the supplementary information to Clause 1.1, Journals with an International Distribution.

### RESPONSE

Vifor reiterated that the journal content was produced in the UK for European and international circulation including UK circulation. Each advertisement contained the international strapline 'Mastering the art of iron therapy' that was ruled in breach in Case AUTH/2411/6/11 [the correct case number was AUTH/2423/7/11]. The journals were not aimed at UK health professionals exclusively however they were in English and produced by a UK publisher. Production and circulation details for the journals were provided.

Vifor UK trained the global teams as soon as the breach of the Code came to its attention. The global teams were trained in December and were now fully aware of the responsibilities the UK and all affiliates had when distributing material within the UK and in particular the requirements to certify advertisements placed in journals produced, published and directed towards the UK. Furthermore, a comprehensive list of journals had been provided to the global teams indicating which would require future review by Vifor in the UK.

Vifor submitted that in addition to the training, internal processes for Vifor's global teams had been revised to take in to account the need for UK certification and avoid similar situations in the future.

In response to a request for further information, Vifor submitted the editorial offices for the three journals at issue were managed through the UK, the journals were typeset in Salisbury and printed in Glasgow.

With respect to the steps taken to communicate the ruling in Case AUTH/2411/6/11 [the correct case number was AUTH/2423/7/11] in relation to the strapline used in the advertisements at issue, Vifor submitted that when it became aware that a Ferinject advertisement had appeared in the NDT Journal, it immediately notified its global colleagues and reiterated the importance of having all journal advertisements certified in accordance with the Code. On 10 January Vifor informed the Authority that an investigation was on-going to determine if any other advertisements had been placed in any other journals. Several telephone conversations and emails were exchanged between Vifor, global marketing and global medical departments in order to identify all advertisements that were placed without Vifor certification. The three advertisements in question were identified and highlighted to the Authority on 20 January. A definitive list identifying which journals required Vifor certification before placement of an advertisement was finalised between global and Vifor on 20 January.

In response to a request for further information, Vifor provided a copy of an email it had sent on 19 August 2011 to global colleagues about the ruling in Case AUTH/2423/7/11.

#### **PANEL RULING**

The Panel noted that it had to consider as a preliminary issue whether advertisements in the journals in question came within the scope of the Code. The supplementary information to Clause 1.1, Journals with an International Distribution, stated that the Code applied to the advertising of medicines in professional journals which were produced in the UK and/or intended for a UK audience. The identification of the country in which a journal was

'produced' was based on factors such as where it was compiled and edited, and where it was typeset, printed and bound, rather than on factors such as the location of the head office of the publisher.

The Panel noted Vifor's submission that the content of each journal was produced in the UK for a European and international circulation. Vifor had submitted that the editorial offices for each were managed through the UK publisher and that the journals were typeset in Salisbury and printed in Glasgow. The Panel therefore considered that the advertisements in these journals fell within the scope of the Code.

The Panel noted that although the advertisements for Ferinject had been placed by Vifor's global office, 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. The advertisements had not been certified in accordance with the UK Code. The Panel thus ruled a breach of Clause 14.1 in relation to each advertisement, as acknowledged by Vifor.

During the consideration of this case the Panel was 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 and had signed the relevant undertaking and assurance in August 2011. Subsequent placement of advertisements with the same strapline was therefore potentially in breach of that undertaking. The Panel noted that Vifor had voluntarily admitted a breach of the Code with regard to certification but not with regard to a breach of undertaking. The Constitution and Procedure did not permit the Panel to consider matters which were not the subject of a complaint or voluntary admission and thus it could not rule on this matter. Nonetheless, the Panel noted that a breach of undertaking was a very serious matter and it requested that Vifor be advised of its concerns in that regard.

<b>Complaint received</b>	<b>24 January 2012</b>
<b>Case completed</b>	<b>23 March 2012</b>