

## **Public Reprimand for Vifor Pharma**

Vifor Pharma has been publicly reprimanded by the Code of Practice Appeal Board for its failure to provide accurate and truthful information to the Code of Practice Panel and its disingenuous approach to responding to the complaints in Cases AUTH/3199/5/19 and AUTH/3224/7/19.

Both cases related to an exchange between a nurse and a Vifor representative who was promoting Ferinject (ferric carboxymaltose for injection or infusion). The materials at issue were an electronic objection handler, the corresponding representatives' briefing material and a follow-up medical information letter sent to the nurse, all of which favourably compared Ferinject with Monofer (iron isomaltoside for injection/infusion) with regard to tolerability and hypersensitivity reactions despite there being little or no difference between the relevant statements in the two summaries of product characteristics (SPCs). The position of the European Medicines Agency (EMA) was that data did not allow clear differentiation between IV iron products and their safety profile in relation to hypersensitivity reactions.

In both cases, Vifor initially stated that it did not claim 'reduced adverse drug reactions (ADRs) when using Ferinject vs Monofer' and that it did not suggest that regulators or the World Health Organisation (WHO) had demonstrated that there were fewer ADRs for Ferinject than for Monofer. A cursory glance at the objection handler would have shown that that statement was incorrect. It was only in response to requests from the Panel for further information, as opposed to the initial requests from the case preparation manager, that Vifor provided a copy of the objection handler and the briefing document which clearly set out differences in the occurrence of hypersensitivity reactions between Ferinject and Monofer in favour of Ferinject and specifically referred to the European Union Drug Regulating Authorities Pharmacovigilance Database and the WHO VigiBase Database. The Panel queried why this information was not provided initially. The Panel noted that self-regulation and the reputation of the industry relied upon full and frank disclosure at the outset.

The Panel was extremely concerned to note that its requests for further information appeared to mark a complete turn-around by Vifor. Having previously provided none of the relevant material and vigorously denied all allegations Vifor now acknowledged potential breaches of the Code - including of Clause 2 in both cases and of Clause 29 in Case AUTH/3199/5/19 - and noted a number of inaccuracies in its original responses; the company only appeared to take this more open and transparent approach following the engagement of external advisors. Although Vifor's abrupt and complete reversal of its position had clarified the matters in hand, the Panel considered that the company's original responses appeared obstructive and uncooperative and in both cases it reported Vifor to the Appeal Board in accordance with Paragraph 8.2 of the Constitution and Procedure.

The two reports were considered at the same Appeal Board meeting during which Vifor submitted that its investigation into the initial response had led to changes at senior levels within the company; further, the company was now committed to change how it promoted its medicines. The Appeal Board was concerned about the length of time it had taken for Vifor to change its approach to the complaint. The Appeal Board welcomed the change in approach from Vifor and its plans to ensure that such issues did not recur. However, the Appeal Board was very concerned about the prevailing company culture within which the initial response was submitted.

In addition to the public reprimand for each case the Appeal Board also decided to require an audit of Vifor's procedures in relation to the Code.

Full details of both cases can be found on the PMCPA website.