

## **PUBLIC REPRIMAND COLONIS** Case AUTH/3240/8/19

Colonis Pharma has been publicly reprimanded by the Code of Practice Appeal Board for its failure to provide complete and accurate information to the Panel (Case AUTH/3240/8/19).

In Case AUTH/3240/8/19 the Code of Practice Panel ruled breaches of the Code including a breach of Clause 2 following a voluntary admission from Colonis that it had included incorrect prescribing information in a promotional letter about Melatonin 1mg/ml oral solution. Colonis accepted the Panel's rulings and provided the requisite undertaking.

During its consideration of this case, the Panel was concerned to note Colonis' submission that the company sent a corrective letter on 23 July to the recipients of the original letter to point out and apologise for the oversight in relation to the incorrect prescribing information. Colonis' submission in this case made no reference to the Medicines and Healthcare products Regulatory Agency (MHRA) in this regard. However, the Panel noted that Colonis' submission to Case AUTH/3239/8/19 stated that the company had received a letter from the MHRA stating that they had been in receipt of several complaints in relation to off-label promotion and following correspondence with the MHRA 'we sent an agreed corrective mailing'. The corrective mailing, dated 24 July, stated 'The MHRA have asked Colonis Pharma to provide a corrective statement...'. The Panel noted that this corrective statement referred to a number of issues with the original promotional letter including the provision of incorrect prescribing information. The Panel queried why Colonis' response to this case (AUTH/3240/8/19) did not refer to the company's correspondence with the MHRA in this regard. Self-regulation relied on complete and accurate responses from companies.

On receipt of the case report for Case AUTH/3240/8/19, as set out in Paragraph 13.4 of the Constitution and Procedure, the Appeal Board was concerned about the incomplete and inaccurate responses and decided that consideration should be given to the imposition of additional sanctions under Paragraph 11.1 of the Constitution and Procedure.

At its subsequent consideration of the matter, the Appeal Board noted that Colonis had failed to state in its response to Case AUTH/3240/8/19 that the corrective letter on 23 July was required by the MHRA. Although the response to Case AUTH/3239/8/19 included a copy of the corrective statement in question the company's letter should have been clearer that the MHRA required a corrective statement to be sent. The information included in Case AUTH/3239/8/19 was clearly relevant to the current case, Case AUTH/3240/8/19. Both responses had been sent to the Authority by Colonis on the same day. The Appeal Board noted that any case under the Code must stand alone and be considered on its individual merits. Case AUTH/3239/8/19 and Case AUTH/3240/8/19 had not been amalgamated under Paragraph 5.1 of the Constitution and Procedure. It was essential that companies had an in depth understanding of the Code and the Constitution and Procedure including responding to complaints. The Appeal Board noted that self-regulation relied, *inter alia*, upon the provision of complete and accurate information from pharmaceutical companies.

The Appeal Board decided that, in accordance with Paragraph 11.3 of the Constitution and Procedure, Colonis should be publicly reprimanded for its failure to provide complete and accurate information to the Panel.