

The ABPI Code of Practice for the Pharmaceutical Industry sets standards for the promotion of medicines for prescribing to health professionals and the provision of information to the public about prescription medicines. Publicity is the main sanction when breaches of the Code are ruled. The latest cases ruled in breach of Clause 2 of the Code (a sign of particular censure) and/or where companies were publicly reprimanded are highlighted below.

Colonis Pharma has breached the ABPI Code of Practice for the Pharmaceutical Industry and brought discredit upon, and reduced confidence in, the pharmaceutical industry. In addition, Colonis was publicly reprimanded.

Colonis Pharma – Case AUTH/3239/8/19

For sending a letter that promoted Melatonin 1mg/ml oral solution for off-label use and prejudiced patient safety, Colonis was ruled in breach of the following clauses of the Code:

- Clause 2** - Bringing discredit upon, and reducing confidence in, the pharmaceutical industry
- Clause 3.2** - Promoting a medicine for an unlicensed indication
- Clause 9.1** - Failing to maintain high standards

Colonis Pharma – Case AUTH/3240/8/19

For failing to identify during the approval process that the incorrect prescribing information had been included in a promotional letter about Melatonin 1mg/ml oral solution, Colonis was ruled in breach of the following clauses of the Code:

- Clause 2** - Bringing discredit upon, and reducing confidence in, the pharmaceutical industry
- Clause 4.1** - Failing to include up-to-date prescribing information
- Clause 9.1** - Failing to maintain high standards

In addition, the Code of Practice Appeal Board required Colonis to be publicly reprimanded for its failure to provide complete and accurate information to the Code of Practice Panel.

The case reports are available at www.pmcpa.org.uk.