PMCPA | Prescription Medicines Code of Practice Authority

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.

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

Janssen-Cilag Ltd – Case AUTH/3436/12/20

Janssen voluntarily admitted that it had failed to maintain oversight and high standards in relation to a nurse-led Stelara (ustekinumab) homecare service and was ruled in breach of the following clauses of the 2019 Code:

Clause 2 - Bringing discredit upon, and reducing confidence in, the pharmaceutical industry
Clause 9.1 - Failing to maintain high standards

In addition, the Code of Practice Appeal Board required Janssen to be publicly reprimanded for its failure to have oversight or control of a patient-facing service for 28 months and for its delay in making its voluntary admission once the errors had come to the company's attention; the company was also required to be audited and re-audited.

Leo Pharma – Case AUTH/3428/11/20

For LEO Pharma UK employees' engagement with a number of posts on the global LinkedIn page, which resulted in multiple breaches of the Code including promoting a medicine prior to the grant of its marketing authorisation, promotion of Enstilar (betamethasone dipropionate/calcipotriol monohydrate) which was inconsistent with its marketing authorisation and misleading with respect to the safety of the medicine, LEO Pharma was ruled in breach of the following clauses of the 2019 Code:

Clause 2 - Bringing discredit upon, and reducing confidence in, the pharmaceutical industry
Clause 3.1 - Promoting an unlicensed medicine
Clause 3.2 - Promotion inconsistent with the summary of product characteristics
Clause 4.1 - Failing to include prescribing information
Clause 4.8 - Failing to include the date on which the promotional material was drawn up or last revised.
Clause 7.2 - Making a misleading claim
Clause 7.9 - Making claims that did not reflect the available evidence regarding possible adverse reactions
Clause 9.1 - Failing to maintain high standards
Clause 14.1 - Failing to certify promotional material
Clause 14.3 - Failing to certify educational material for the public
Clause 26.1 - Promoting a prescription only medicine to the public

Leo Pharma – Case AUTH/3527/6/21

For failures in relation to disclosure of payments made to patient organisations in 2019 and its lack of oversight of overseas affiliate's interactions with UK based patient organisations, Leo Pharma was ruled in breach of the following clauses of the 2019 Code:

Clause 2 - Bringing discredit upon, and reducing confidence in, the pharmaceutical industry
Clause 9.1 - Failing to maintain high standards
Clause 14.3 - Failing to certify
Clause 27.7 - Failing to disclose an accurate list of patient organisations to which it provided financial support and/or significant indirect/non-financial support

Teva – Case AUTH/3451/1/21

For failing to include an adverse event reporting statement within the content of promotional webpages themselves in relation to five respiratory products, failing to include such a statement anywhere in the materials for Tymbrineb (tobramycin) and Qvar (beclometasone dipropionate) and for only including the relevant statement within the prescribing information for Cinqaero (reslizumab) when it was subject to additional monitoring, Teva was ruled in breach of the following clauses of the 2019 Code:

Clause 2 - Bringing discredit upon, and reducing confidence in, the pharmaceutical industry
Clause 3.2 - Promoting a medicine for an unlicensed indication
Clause 4.1 - Failing to include prescribing information
Clause 4.6 - Failing to include a clear, prominent statement as to where prescribing information could be found
Clause 4.9 - Failing to include information about how to report adverse events
Clause 9.1 - Failing to maintain high standards
Clause 28.1 - Failing to clearly separate sections for each target audience on a website and identifying the intended audience at the outset

The case reports, interim case report and public reprimand are available at www.pmcpa.org.uk.