PMCPA

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 only 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) are highlighted below.

Leo Pharma and AstraZeneca have breached the ABPI Code of Practice for the Pharmaceutical Industry and brought discredit upon, and reduced confidence in, the pharmaceutical industry.

LEO Pharma – Case AUTH/3503/4/21

For the unbalanced and misleading presentation of information and the failure to provide up-to-date safety information in relation to its website promoting Kyntheum (brodalumab), Leo 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 - Promotion inconsistent with the SPC
Clause 4.10 - Failing to show an inverted black equilateral triangle to denote that additional monitoring is required in relation to adverse reactions
Clause 7.2 - Making misleading claims
Clause 7.3 - Making misleading comparisons
Clause 7.4 - Making unsubstantiated claims
Clause 7.9 - Making a claim that did not reflect the available evidence regarding possible adverse reactions
Clause 7.10 - Not encouraging the rational use of the medicine
Clause 9.1 - Failing to maintain high standards

LEO Pharma – Case AUTH/3548/7/21

For the improper conduct by a senior Leo employee in actively seeking confidential discount price information about a competitor product from NHS staff, for the purposes of Leo's own commercial interests, the company was ruled in breach of the following clauses of the 2016 Code:

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

AstraZeneca – Case AUTH/3585/11/21

For the misleading omission of the upper limit for the dosing of Symbicort (budesonide, formoterol fumarate) and the strong recommendation in the SPC for patients using more than 16 actuations daily to seek medical advice on the AstraZeneca medicines website; and for failing to include the non-proprietary name for three different medicines and Symbicort prescribing information or a statement as to where it could be found on the Trixeo (formoterol/budesonide/glycopyrronium) website, AstraZeneca was ruled in breach of the following clauses of the 2021 Code:

Clause 2 - Bringing discredit upon, and reducing confidence in, the pharmaceutical industry
Clause 5.1 - Failing to maintain high standards
Clause 6.1 - Providing insufficiently complete information such that it was misleading
Clause 6.2 - Proving misleading information which was not capable of substantiation
Clause 12.1 - Failing to include prescribing information
Clause 12.3 - Failing to include the non-proprietary name immediately adjacent to the most prominent display of a brand name
Clause 12.4 - Failing to include prescribing information in digital material or by way of a clear, prominent, direct single click
Clause 12.6 - Failing to include a clear, prominent statement as to where prescribing information could be found

AstraZeneca – Case AUTH/3618/3/22

For misleading dosing claims on the Forxiga (dapagliflozin) promotional website, which had qualifying and important safety information for patients with severe hepatic impairment in a footnote that could have easily been missed by a health professional, AstraZeneca was ruled in breach of the following clauses of the 2021 Code:

Clause 2 - Bringing discredit upon, and reducing confidence in, the pharmaceutical industry
Clause 5.1 - Failing to maintain high standards
Clause 6.1 - Providing misleading information
Clause 6.2 - Providing misleading information which was not capable of substantiation
Clause 11.2 - Promotion inconsistent with the summary of product characteristics
Clause 14.4 - Not encouraging the rational use of a medicine

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