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 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) and/or where companies were required to issue a corrective statement or were publicly reprimanded, are highlighted below.

Genzyme has breached the ABPI Code of Practice for the Pharmaceutical Industry and brought discredit upon, and reduced confidence in, the pharmaceutical industry. In addition, Genzyme has been required to issue a corrective statement.

Genzyme – Case AUTH/2721/7/14

For making a presentation about Fabrazyme (agalsidase beta), to an expert advisory group, that was, *inter alia*, misleading, inconsistent with the Fabrazyme SPC and disparaging of a competitor product, Genzyme 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 - Making claims inconsistent with the SPC.
Clause 7.2 - Making misleading claims.
Clause 7.3 - Making misleading comparisons.
Clause 7.4 - Making unsubstantiated claims.
Clause 7.6 - Referring to published studies without giving clear references.
Clause 7.8 - Providing misleading graphs.
Clause 7.10 - Not encouraging the rational use of a medicine.
Clause 8.1 - Disparaging a competitor product.
Clause 9.1 - Failing to maintain high standards.
Clause 14.1 - Failing to certify material in its final form.

The Code of Practice Appeal Board was so concerned about the content of the presentation, its potential effects and impression given, including the disregard for patient safety, that it decided to require Genzyme to issue a corrective statement to all of those who had been at the meeting or had received a pre-meeting copy of the material.

The full case report, which includes the wording of the corrective statement, was published in the PMCPA May Code of Practice Review and is also available at **www.pmcpa.org.uk**.

AstraZeneca has breached the ABPI Code of Practice for the Pharmaceutical Industry and in addition it has been publicly reprimanded and required to issue a corrective statement.

AstraZeneca – Case AUTH/2793/9/15

For producing a leavepiece which provided misleading instructions on how to use the EMIS Web clinical system such that controlled (based on HbA1c levels) type 2 diabetic patients might be inappropriately treated with Forxiga (dapagliflozin), AstraZeneca was ruled in breach of the following clauses of the Code:

Clause 3.2 - Making claims inconsistent with the SPC.
Clause 7.2 - Making misleading claims.
Clause 9.1 - Failing to maintain high standards.

The Code of Practice Panel reported the company to the Code of Practice Appeal Board for providing inaccurate information. The Appeal Board considered that it was fundamental for effective self-regulation for companies to provide accurate information to the Panel and for failing to do so and for exercising poor governance it publicly reprimanded AstraZeneca. The Appeal Board was concerned that use of the leavepiece might lead to the inappropriate prescription of Forxiga, and it required AstraZeneca to issue a corrective statement to recipients of the leavepiece to clarify the position.

The full case report, which includes the wording of the corrective statement, was published in the PMCPA May Code of Practice Review; the public reprimand appeared on the front cover. The case report and the Code of Practice Review are available at **www.pmcpa.org.uk**.

The Prescription Medicines Code of Practice Authority (PMCPA) was established by The Association of the British Pharmaceutical Industry (ABPI) to operate the ABPI Code of Practice for the Pharmaceutical Industry independently of the ABPI. The PMCPA is a division of the ABPI. The Code covers the promotion of medicines for prescribing to health professionals and the provision of information to the public about prescription only medicines.

If you have any concerns about the activities of pharmaceutical companies in this regard, please contact the PMCPA at 7th Floor, 105 Victoria St, London, SW1E 6QT or email: complaints@pmcpa.org.uk.

The Code and other information, including details about ongoing cases, can be found on the PMCPA website: **www.pmcpa.org.uk**